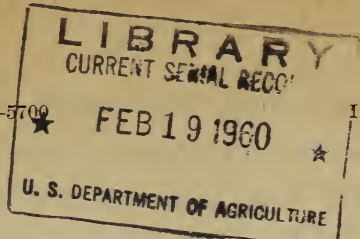


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# U.S. Department of Health, Education, and Welfare

## FOOD AND DRUG ADMINISTRATION

### NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

5661-5700

### DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs which are required at time of interstate shipment to bear a label containing the statement "Caution: Federal law prohibits dispensing without prescription," and which were dispensed after such shipment without a prescription or by refilling a prescription without authorization. This dispensing was contrary to Section 503(b)(1) and thereby resulted in the dispensed drugs being misbranded while held for sale.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D.C., January 27, 1960.

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## VIOLATIVE SALES OF PRESCRIPTION DRUGS

5661. (F.D.C. No. 41160. S. Nos. 39-391 M, 57-228 M, 57-237 M, 57-240 M, 57-246 M, 57-644 M.)

INFORMATION FILED: 8-4-58, S. Dist. Fla., against James Drug Shop, Inc., Miami, Fla., Jeanne Louise Scheibler (president of the corporation), and Warren D. Morrison (pharmacist).

CHARGE: Between 7-31-57 and 8-27-57, *Metandren Linguets* (count 5) and *Carbital capsules* (count 6) were each dispensed once without a prescription and *secobarbital sodium capsules* (counts 1, 2, 3 and 4) were dispensed 4 times upon request for prescription refills without authorization by the prescriber.

PLEA: Guilty by the corporation to all 6 counts of the information; by Scheibler to count 4; and by Morrison to counts 1, 2, 3, 5, and 6.

DISPOSITION: 9-8-58. The corporation was fined \$600 and each individual was placed on probation for 2 years.

5662. (F.D.C. No. 41165. S. No. 57-232 M.)

INFORMATION FILED: 3-12-58, S. Dist. Fla., against Edward Kunitz, t/a Majorca Drug Store, Coral Gables, Fla.

CHARGE: On 8-5-57, *methyltestosterone tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 6-16-58. Probation for 1 year.

5663. (F.D.C. No. 42032. S. Nos. 2-388/91 P.)

INFORMATION FILED: 11-6-58, S. Dist. Fla., against Hubert L. Danese, t/a Danese's Pharmacy, Jacksonville, Fla.

CHARGE: On 2-5-58, *Amytal Sodium capsules* were dispensed twice, and *Amytal tablets* and *Biphedamine Sodium capsules* were each dispensed once without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 2-6-59. Sentence of 2 years in prison and probation for 3 years, to commence upon termination of prison sentence.

5664. (F.D.C. No. 41194. S. Nos. 39-380/1 M, 39-384 M, 39-387 M, 57-411 M.)

INFORMATION FILED: 4-17-58, S. Dist. Ga., against Beach Drug Co., Inc., Savannah Beach, Ga., and Howard H. O'Brien (president).

CHARGE: Between 6-12-57 and 8-14-57, *Tuinal capsules* were dispensed 3 times upon request for prescription refills without authorization by the prescriber and *Metandren Linguets* and *Banthine tablets* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 5-12-58. Each defendant fined \$50 and placed on probation for 2 years.

5665. (F.D.C. No. 42165. S. Nos. 4-060/3 P, 4-065 P, 4-073/5 P, 4-077 P.)

INFORMATIONS FILED: An information was filed on 11-11-58, in the W. Dist. Va., against Woodrow C. Brightwell, Roanoke, Va., relating to the dispensing of *Sulfacombin No. 4 tablets* (containing a mixture of sulfadiazine, sulfamerazine, and sulfacetimide), *Sedacaps capsules* (containing a mixture of dextro-

amphetamine sulfate, phenobarbital, and pentobarbital sodium), *Raupen Comp. No 2 tablets* (containing a mixture of *Rauwolfia serpentina*, mannitol hexantrate, and rutin), *chloral hydrate capsules*, *Aspirin Comp. with phenobarbital tablets*, *penicillin G potassium tablets*, and *phenobarbital tablets*. Another information was filed on the same date in the W. Dist. Va., against Woodrow C. Brightwell, Chester L. Davis, and Lewis D. Rowland, Roanoke, Va., relating to the dispensing of *sulfathiazole tablets*.

CHARGE: Between 3-25-56 and 9-12-57, *Sulfacombin No. 4 tablets* were dispensed twice, and *Sedacaps capsules*, *Raupen Comp. No. 2 tablets*, *chloral hydrate capsules*, *Aspirin Comp. with phenobarbital tablets*, *penicillin G potassium tablets*, and *phenobarbital tablets* were each dispensed once by Woodrow Brightwell without a prescription. On 9-25-58, *sulfathiazole tablets* were dispensed once by Woodrow Brightwell, Chester Davis, and Lewis Rowland without a prescription.

PLEAS: Nolo contendere.

DISPOSITION: 11-13-58. Brightwell was fined \$500, and Davis and Rowland were each fined \$250.

5666. (F.D.C. No. 41140. S. No. 68-696 M.)

INFORMATION FILED: 5-20-58, E. Dist. N.Y., against Ralph F. DePalma, Jr., t/a Tap Pharmacy, Brooklyn, N.Y.

CHARGE: On 7-8-57, *chloramphenicol capsules* were dispensed once upon request for a prescription refill without authorization by the prescriber.

PLEA: Guilty.

DISPOSITION: 6-20-58. \$300 fine.

5667. (F.D.C. No. 42034. S. Nos. 29-767 P, 29-769 P, 29-781 P, 30-773 P.)

INFORMATION FILED: 10-28-58, Dist. N.J., against Sol Wolfson, t/a Northfield Pharmacy, Livingston, N.J., and Don Rubin (pharmacist).

CHARGE: Between 1-7-58 and 2-21-58, *Seconal Sodium capsules* were dispensed twice and *Dexedrine Sulfate capsules* and *Butisol Sodium Elixir* were each dispensed once, upon requests for prescription refills without authorization by the prescribers.

PLEA: Guilty by Wolfson to all counts of the information and by Rubin to the count involving the dispensing of *Dexedrine Sulfate capsules*.

DISPOSITION: 2-20-59. Wolfson—\$3,000 fine; and Rubin—\$300 fine.

5668. F.D.C. No. 42037. S. Nos. 29-825 P, 31-002/3 P.)

INFORMATION FILED: 10-6-58, Dist. N. J., against Walter Brodzinski, t/a Jung's Pharmacy, Newark, N.J.

CHARGE: Between 3-14-58 and 3-24-58, *Dexedrine Sulfate tablets* were dispensed twice, and *Seconal Sodium capsules* were dispensed once upon requests for prescription refills without authorization by the prescriber.

PLEA: Guilty.

DISPOSITION: 10-31-58. Fine of \$250 and probation for 1 year.

5669. (F.D.C. No. 41761. S. Nos. 65-288 M, 65-291 M, 65-299 M, 83-474/5 M, 16-463/4 P.)

INFORMATION FILED: 7-28-58, N. Dist. Ohio, against David Weisenberg, t/a Liberty Cut Rate Drug Co., Cleveland, Ohio, and Fred S. Levine (an employee).



CHARGE: Between 10-11-57 and 1-20-58, *amphetamine sulfate tablets* were dispensed 3 times and *penicillin tablets* were dispensed 4 times without a prescription.

PLEA: Guilty.

DISPOSITION: 9-5-58. Weisenberg fined \$1,400 and Levine fined \$200.

5670. (F.D.C. No. 41759. S. Nos. 60-364 M, 11-775 P, 11-777/9 P.)

INFORMATION FILED: 8-21-58, E. Dist. Mich., against the **Sproat Drug Co. (a partnership)**, **Detroit, Mich.**, and **Paul Bloch (pharmacist)**.

CHARGE: Between 12-23-57 and 2-26-58, *Dexedrine Sulfate tablets* were dispensed 3 times, and *Metandren Linguets* and *Doriden tablets* were each dispensed once without a prescription.

PLEA: Guilty by the partnership to all 5 counts of the information, and nolo contender by Bloch to the count involving the dispensing of *Doriden tablets*.

DISPOSITION: 11-21-58. Partnership—\$750 fine; individual—\$250 fine.

5671. (F.D.C. No. 42025. S. Nos. 8-864/7 P, 8-869 P, 9-222 P.)

INFORMATION FILED: 9-23-58, W. Dist. Pa., against **Irwin Schulman (pharmacist)**, **Pittsburgh, Pa.**

CHARGE: Between 3-27-58 and 4-17-58, *Seconal Sodium capsules* were dispensed 3 times, *capsules containing a mixture of secobarbital sodium and amobarbital sodium* were dispensed twice, and *Gantrisin tablets* were dispensed once upon requests for prescription refills without authorization by the prescribers.

PLEA: Nolo contendere.

DISPOSITION: 1-26-59. \$400 fine, plus costs.

5672. (F.D.C. No. 42020. S. Nos. 8-843/50 P.)

INFORMATION FILED: 10-1-58, W. Dist. Pa., against **Meyer's Drug, Inc., Pittsburgh, Pa.**, and **Marvin Barent (vice-president)**.

CHARGE: Between 3-21-58 and 4-15-58, *Gantrisin tablets* and *Seconal Sodium capsules* were each dispensed 3 times upon requests for prescription refills without authorization by the prescriber, and *Gantrisin tablets* and *AM Plus capsules* were each dispensed once without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 1-27-59. Each defendant was fined \$300, plus costs, on count 1 of the information, and sentence was suspended as to each defendant on the other 7 counts of the information.

5673. (F.D.C. No. 41733. S. Nos. 30-999 M, 64-917 M, 65-548/50 M, 82-994 M.)

INFORMATION FILED: 7-21-58, S. Dist. Ind., against **Clearwater & McCarty (a partnership)**, **Rockville, Ind.**, **Forrest E. Clearwater (partner)**, and **Nathan J. Lane (pharmacist)**.

CHARGE: Between 10-10-57 and 12-9-57, *meprobamate tablets* (counts 1, 2, and 4) were dispensed 3 times, and *Achrocidin tablets* (count 3), *Mystecclin capsules* (count 5), and *Dexedrine Spansule capsules* (count 6), were each dispensed once without a prescription.

PLEA: Guilty by the partnership to all 6 counts of the information; by Forrest Clearwater to counts 2 to 6 of the information; and by Nathan Lane to counts 2 and 3.

DISPOSITION: 12-18-58. The court fined the partnership \$300, Forrest Clearwater \$1,250, and Nathan Lane \$50, plus costs.

5674. (F.D.C. No. 42017. S. Nos. 11-797 P, 14-803 P, 14-811 P.)

INFORMATION FILED: 9-30-58, S. Dist. Ind., against Sidney Williams, t/a Williams Prescription Pharmacy, Anderson, Ind.

CHARGE: Between 4-8-58 and 4-17-58, *pentobarbital sodium capsules* were dispensed twice, and *penicillin G potassium tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 11-26-58. Fine of \$2,250, plus costs.

5675. (F.D.C. No. 42024. S. Nos. 11-989 P, 11-991/2 P.)

INFORMATION FILED: 11-28-58, N. Dist. Ind., against the Broadway Drug Store (a partnership), East Chicago, Ind., and Thomas S. Upshaw (manager and pharmacist for the partnership).

CHARGE: Between 4-9-58 and 4-17-58, *Dexedrine Sulfate tablets*, *Metandren Linguets*, and *dextro-amphetamine sulfate capsules* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 12-29-58. Partnership fined \$300, plus costs, and individual fined \$100.

5676. (F.D.C. No. 42033. S. Nos. 72-181/2 M, 72-230/2 M, 12-165 P, 14-741 P.)

INFORMATION FILED: 10-13-58, N. Dist. Ill., against Dore Drugs, Inc., Chicago, Ill., and Wilber Dorfman (president and apprentice pharmacist for the corporation).

CHARGE: Between 9-7-57 and 1-20-58, *Pentids tablets* and *penicillin G potassium tablets* were each dispensed twice, *AM Plus capsules*, *Erroder-Plus capsules*, and *dextro-amphetamine sulfate capsules* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 11-3-58. Corporation fined \$525 and individual fined \$475, plus costs.

5677. (F.D.C. No. 41756. S. Nos. 19-888 P, 19-891 P, 19-896 P.)

INFORMATION FILED: 7-10-58, Dist. Nebr., against Alfred L. Walsh (also known as "Knobby" Walsh), Fremont, Nebr.

CHARGE: Between 2-19-58 and 3-5-58, *amphetamine sulfate tablets* were dispensed three times without a prescription.

PLEA: Guilty.

DISPOSITION: 9-17-58. The defendant was placed on probation for 1 year.

5678. (F.D.C. No. 41145. S. No. 34-476 M.)

INFORMATION FILED: 1-16-58, Dist. Nebr., against Doran Hertel, Omaha, Nebr.

CHARGE: On 5-4-57, *Placidyl* (Ethchlorvynol, Abbott) *capsules* were dispensed once without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 11-6-58. Defendant was fined \$250, plus costs, and placed on probation for 18 months.

5679. (F.D.C. No. 41762. S. Nos. 81-664 M, 82-241 M.)

INFORMATION FILED: 9-23-58, S. Dist. Tex., against Ernest K. Keith, and Jack H. Glazer (partners in the partnership of Palms Pharmacy), Houston, Tex.

CHARGE: Between 5-7-57 and 11-3-57, *thyroid tablets* and *meprobamate tablets* were each dispensed once without a prescription.

PLEA: Nolo contendere by Keith to dispensing the *thyroid tablets*; and by Glazer to dispensing the *meprobamate tablets*.

DISPOSITION: 10-24-58. \$250 fine against each defendant.

5680. (F.D.C. No. 39200. S. Nos. 51-629 M, 51-641/2 M.)

INDICTMENT RETURNED: 1-10-57, N. Dist. Tex., against Thomas Guy Brown, Dumas, Texas.

CHARGE: Between 3-13-56 and 3-23-56, *dextro-amphetamine hydrochloride tablets* were dispensed twice and *dextro-amphetamine sulfate tablets* were dispensed once without a prescription from a practitioner licensed by law to administer the drugs.

PLEA: Not guilty.

DISPOSITION: On 2-11-57, the case came to trial before a jury and, on 2-13-57, the jury returned a verdict of guilty. The defendant was fined \$500, given a prison sentence of 5 months, and placed on probation for 4 years. The case was appealed to the United States Court of Appeals for the Fifth Circuit; and, on 1-3-58, that court handed down the following opinion (250 F. 2d 745):

TUTTLE, *Circuit Judge*: "This is an appeal from the conviction of a physician for the violation of provisions of the Food, Drug and Cosmetic Act that prohibits the *dispensing* of certain potentially harmful drugs, transported in interstate commerce, without a *prescription*.

"The evidence fully warranted the jury's finding that the appellant, a practicing physician in Dumas, Texas, sold to two Federal agents, whom he supposed to be truck drivers, three separate lots of dextro-amphetamine hydrochloride tablets<sup>1</sup> that had been shipped in interstate commerce; that prior to dispensing them Dr. Brown had not prepared or given them any prescription and had not physically examined either of them and had not questioned them or 'prescribed' a dosage or otherwise attempted to acquaint himself with either the physical condition or needs of either man.

"The statute under which the three-count indictment was brought makes illegal and punishable as for a misdemeanor, under circumstances here present, a violation of the following provisions of 21 U.S.C.A. § 353 (b) (1):

A drug intended for use by man which . . . .

(B) Because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such a drug;

. . . . .  
shall be dispensed only (i) upon a written prescription of a practitioner licensed by law to administer such drug, or (ii) upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist, or (iii) by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist. The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale.

21 U.S.C.A. § 353 (b) (2).

<sup>1</sup> The testimony, denied by the accused, was to the effect that the agent Spivak obtained 1000 5-mg. tablets on March 10th, 1000 10-mg. tablets on March 22nd, and that, in the presence of Spivak, another agent, Keeting, received 1000 5-mg. tablets on March 23rd.



"Although the appellant denies the sales, implying that the transactions with the two agents were of quite a different nature, he makes no contention that there was not sufficient evidence to sustain the conviction if the terms of this statute reach a regularly licensed physician who sells these covered drugs under the circumstances outlined. The burden of his defense is that the provisions of the Act do not apply to the act of dispensing drugs by a licensed physician.

"No decided case in which an appellate court has precisely held this law applicable to the conduct of a regularly licensed physician has been called to our attention. The Court of Appeals for the Tenth Circuit affirmed a conviction of one who held himself out to be a doctor, but who had not obtained a medical license in *Archambault v. United States*, 10 Cir., 224 F. 2d 925. The District Court for the Western District of Missouri construed the law as here contended for by the United States where it entered a judgment of conviction on a plea of *nolo contendere* against a doctor who dispensed pills of the prescribed type without an examination or prescription. In sentencing the prisoner, the district judge, now Supreme Court Justice Whittaker, said:

Your error lies in the fact that, having a license to practice medicine, you have assumed that it was a license to peddle pills, and that is not the law. People came to you, Doctor, and without an examination or any prescription, just ordered pills and you would ask them, "Do you want the red or the yellow?"—and you just handed out the pills, these barbiturates and sex hormones, [sic] without any examination or prescription. You did that to those Government agents who came in there, not once but half a dozen times.

Now, there seems to be some concept among the members of the medical profession that to have a license to deal in medicine carries a license to deal in barbiturates. That is not the law. The medical profession might just as well understand it. If I come to you for treatment and you, in your medical capacity examine me, and after examination determine that certain barbiturates would be beneficial to me, then you have a right to write a prescription to me, and then I have a right to get them and use them, but not otherwise.

*United States v. Amin Boutros*, (D.C.W.D. Mo.)

No. 19,304—Cr. Decided Dec. 23, 1955.

"The language of the statute, considered alone, is certainly broad enough to make criminal what was done here. It says expressly that these pills 'shall be dispensed only (i) upon a written prescription of a practitioner licensed by law to administer such drug, or (ii) upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist, or (iii) by refilling any such . . . .'. The 3000 tablets were acquired by the 'purchasers,' who were not 'patients,' without either a written or oral prescription, no matter how broadly the word 'prescription' is to be construed.

"Appellant argues only that although the language is broad enough to include physicians, the statute must be interpreted differently and for this proposition he refers to the discussion in the legislative history of the apparent purpose to make the requirements applicable to 'druggists.' But we do not need to refer to the legislative history of this particular act to construe the statute. The Supreme Court has on several occasions held that the purpose of the legislation is the protection of the people from dangerous products which are shipped in interstate commerce. *United States v. Dotterweich*, 320 U.S. 277; *United States v. Sullivan*, 332 U.S. 689. Further, the Court in the Sullivan case, said:

. . . there is no canon against using common sense in reading a criminal law, so that strained and technical constructions do not defeat its purpose by creating exceptions from or loopholes in it. 332 U.S. 689, 693.

"Moreover, the Supreme Court has also construed the word 'prescription' as used in other related Federal legislation. Recognizing, as we do, that under the Harrison Narcotic Act, the question of good faith treatment of patients may be involved, nevertheless we find, in a Harrison Act case, pertinent

language describing a 'prescription.' The Court answered a certified question from the Court of Appeals for the Sixth Circuit:

3. If a practicing and registered physician issues an order for morphine to an habitual user thereof, the order not being issued by him in the course of professional treatment in the attempted cure of the habit, but being issued for the purpose of providing the user with morphine sufficient to keep him comfortable by maintaining his customary use, is such order a physician's prescription under exception (b) of § 2?

*Webb v. United States*, 249 U.S. 96, 99.

"The answer, obvious it seems to any who consider the matter, was:

As to question three—to call such an order for the use of morphine a physician's prescription would be so plain a perversion of meaning that no discussion of the subject is required. That question should be answered in the negative.

*Webb v. United States*, 249 U.S. 96, 100.

"What was there said by the Supreme Court answers, we think, appellant's objection to the court's charge that the jury might properly consider whether a doctor-patient relationship existed.<sup>2</sup> The inquiry whether there was a bona fide relationship of patient and doctor bears on the question whether there had ever been a 'prescription' for the agents. The court thus broadened the term to something more than written paper, which really benefitted the accused. The jury, under this charge, could have found that Dr. Brown 'prescribed' for the men if the jury had found the existence of a doctor-patient relationship which appellant testified vaguely did exist, at least as to two of the sales. There was no error in submitting this issue to the jury.

"We conclude that the jury had ample grounds for finding that Dr. Brown dispensed the tablets without prescription and we find that such action is prohibited under the law, even when done by a regularly licensed physician.

"The judgment is **AFFIRMED**."

The defendant filed a petition for a writ of certiorari with the United States Supreme Court, and on 4-28-58 the petition was denied (356 U.S. 938).

**5681. Supplement to notice of judgment on drugs and devices No. 4844. Violation of probation.** (F.D.C. No. 36594. S. Nos. 44-997/8P.)

**VIOLATION OF PROBATION:** About 3-4-59, an application was filed for revocation of probation imposed against **Homer N. Archambault**, the defendant in the case reported in the above-mentioned notice of judgment. It was alleged in the application that the defendant had, on 1-17-59, dispensed a number of *sulfadiazine tablets* without a prescription.

**DISPOSITION:** After a hearing on 3-11-59, the court found the defendant had violated the conditions of his probation. Thereupon the court revoked the order of probation previously entered and sentenced the defendant to 11 months and 15 days in jail.

**5682.** (F.D.C. No. 39834. S. Nos. 41-601 M, 41-603 M, 41-610 M.)

**INFORMATION FILED:** 12-11-57, W. Dist. N.Y., against **Singer's Cut Rate Drug Store, Inc., Buffalo, N.Y., Morris Olodort (store manager and pharmacist), and Abraham C. Taylorson (pharmacist).**

<sup>2</sup> The charge was:

"If you find that the defendant did dispense the original contents of Government Exhibits 1, 2 and 3, two of them to the Government witness Spivak, and the other to the Government witness Keeting, then in determining whether he dispensed the drugs therein on prescription, you may properly consider whether a doctor-patient relationship existed between the defendant and the person to whom you find he sold the bottle of drug in each instance, whether he considered the individual needs of the person to whom he dispensed the drug, the quantity of the drug dispensed and the manner in which he supervised the use of the drug. The fact that the defendant is a physician licensed under the laws of Texas does not exempt him from responsibility for any violation of the terms of the Federal law in question."



CHARGE: Between 6-15-56 and 7-11-56, *secobarbital sodium capsules* (count 1) were dispensed once and *capsules containing a mixture of secobarbital sodium and amobarbital sodium* (counts 2 and 3) were dispensed twice without a prescription.

PLEA: Nolo contendere by the corporation; by Olodort to all counts; and by Taylorson to counts 1 and 3.

DISPOSITION: 7-22-59. Corporation—\$400 fine; Olodort and Taylorson—\$50 fine each.

5683. (F.D.C. No. 40441. S. Nos. 41-862 M, 41-873 M, 41-875 M, 42-183 M, 42-185 M, 42-189/91 M.)

INFORMATION FILED: 12-23-57, W. Dist. N.Y., against Cogan's Pharmacy (a corporation), Buffalo, N.Y., Jacob E. Epstein (vice president and secretary-treasurer), and Gerald E. Warmus (pharmacist).

CHARGE: Between 8-17-56 and 1-28-57, *capsules containing secobarbital sodium* (counts 1, 2, and 4) were dispensed three times, *tablets containing dextro-amphetamine sulfate* (count 3) and *tablets containing meprobamate* (count 5) were each dispensed once, and *tablets containing sulfisoxazole* (counts 6 and 7) were dispensed twice upon requests for prescription refills without authorization from a prescriber; and *tablets containing dextro-amphetamine sulfate* (count 8) were dispensed once without a prescription.

PLEA: Nolo contendere by the corporation and Epstein to all counts and by Warmus to counts 2, 3, 5, 7, and 8.

DISPOSITION: 7-22-59. Corporation—\$400 fine; Epstein and Warmus—\$50 each fine.

5684. (F.D.C. No. 38546. S. Nos. 4-508 M, 4-561 M, 4-570 M, 4-713 M, 4-719 M.)

INFORMATION FILED: 12-11-57, W. Dist. N.Y., against Frank Stein, t/a Day's Cut Rate Drug Store, Buffalo, N.Y., and Irwin Rubin (pharmacist).

CHARGE: Between 4-18-55 and 5-11-55, *butabarbital sodium elixir* (count 1) was dispensed once and *Gantrisin tablets* (counts 2-5) were dispensed four times upon requests for prescription refills without authorization from a prescriber.

PLEA: Nolo contendere by Frank Stein to all counts and by Irwin Rubin to counts 3, 4, and 5.

DISPOSITION: 7-22-59. Frank Stein—\$400 fine; Irwin Rubin—\$50 fine.

5685. (F.D.C. No. 38549. S. Nos. 4-511 M, 4-514 M, 4-562 M, 4-564 M, 4-718 M.)

INFORMATION FILED: 12-11-57, W. Dist. N.Y., against Nathan Pigovat, t/a Nate's Pharmacy, Buffalo, N.Y., and Benjamin Pigovat (pharmacist).

CHARGE: Between 4-18-55 and 5-11-55, *butabarbital sodium elixir* (counts 1 and 2) was dispensed twice and *Gantrisin tablets* (counts 3-5) were dispensed three times upon requests for prescription refills without authorization from a prescriber.

PLEA: Nolo contendere by Nathan Pigovat to all counts and by Benjamin Pigovat to counts 2, 4, and 5.

DISPOSITION: 7-22-59. Nathan Pigovat—\$400 fine; Benjamin Pigovat—\$50 fine.

5686. (F.D.C. No. 38550. S. Nos. 4-509 M, 4-513 M, 4-516 M, 4-534 M, 4-563 M, 4-565 M.)

INFORMATION FILED: 12-11-57 W. Dist. N.Y., against Park-Sher Drug Co., Inc., Tonawanda, N.Y., Albert Lettman (vice president and pharmacist), and Gerald T. Hooley (pharmacist).

CHARGE: Between 4-18-55 and 5-11-55, *butabarbital sodium elixir* (counts 1-4) was dispensed four times and *Gantrisin tablets* (counts 5 and 6) were dispensed twice upon requests for prescription refills without authorization from a prescriber.

PLEA: Nolo contendere by the corporation and Lettman to all counts, and by Hooley to counts 4, 5, and 6.

DISPOSITION: 7-22-59. Corporation—\$400 fine; Lettman and Hooley—each \$50 fine.

5687. (F.D.C. No. 40475. S. Nos. 63-991/2 M, 64-674 M, 64-676 M, 64-799 M.)

INFORMATION FILED: 1-24-58, W. Dist. N.Y., against Thomas M. Infantino, t/a Allen Pharmacy, Buffalo, N.Y.

CHARGE: Between 3-10-57 and 7-8-57, *tablets containing amphetamine sulfate* were dispensed four times, and *capsules containing a mixture of secobarbital sodium and amobarbital sodium* were dispensed once without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 7-22-59. \$400 fine.

5688. (F.D.C. No. 41192. S. Nos. 68-683 M, 68-688 M.)

INFORMATION FILED: 4-16-59, E. Dist. N.Y. against Leonard Levinson, t/a Glenwood Pharmacy, Brooklyn, N.Y.

CHARGE: Between 6-11-57 and 6-14-57, *chloramphenicol capsules* and *Dexedrine Sulfate tablets* were each dispensed once upon requests for prescription refills without authorization from a prescriber.

PLEA: Guilty.

DISPOSITION: 6-23-59. \$600 fine and probation for 1 year.

5689. (F.D.C. No. 41747. S. Nos. 30-033 P, 30-803 P.)

INFORMATION FILED: 8-29-58, S. Dist. N.Y. against Leon Lerea (a pharmacist), Scarsdale, N.Y.

CHARGE: Between 2-4-58 and 2-7-58, *Seconal Sodium capsules* and *Dexedrine Sulfate tablets* were each dispensed once upon request for prescription refills without authorization from a prescriber.

PLEA: Guilty.

DISPOSITION: 2-5-59. \$250 fine.

5690. (F.D.C. No. 41723. S. Nos. 3-025 M, 76-458/9 M, 76-619 M, 76-737 M, 90-342/3 M, 6-841 P.)

INFORMATION FILED: 6-18-58, Dist. Mass., against Olga G. Kirsch, t/a Harold Pharmacy, Revere (Beachmont), Mass.

CHARGE: Between 10-23-57 and 1-7-58, *secobarbital sodium capsules* and *dextro-amphetamine sulfate tablets* were each dispensed 3 times and *pentobarbital sodium capsules* were dispensed twice upon requests for prescription refills without authorization from a prescriber.

PLEA: Guilty.

DISPOSITION: 2-16-59. \$750 fine; jail sentence of 6 months suspended, and defendant placed on probation for 1 year.

5691. (F.D.C. No. 41745. S. Nos. 60-752/4 M, 76-296 M, 76-299 M, 76-442/3 M, 76-595 M.)

INFORMATION FILED: 12-16-58, Dist. Mass., against Herman Seligman, t/a Roma Pharmacy, Boston, Mass.

CHARGE: Between 10-7-57 and 11-13-57, *Gantrisin tablets*, *cortisone acetate tablets*, and *Butazolidin tablets* were each dispensed twice upon requests for prescription refills without authorization from a prescriber, and *Gantrisin tablets* and *Premarin tablets* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 6-29-59. \$1,000 fine; jail sentence of 1 year suspended, and defendant placed on probation for 2 years.

5692. (F.D.C. No. 41738. S. Nos. 76-172 M, 76-174 M, 76-180 M, 76-516/7 M, 76-520 M, 76-641/2 M.)

INFORMATION FILED: 12-16-58, Dist. Mass., against Peter Eacmen, t/a Cottage Pharmacy, Boston (Dorchester), Mass.

CHARGE: Between 8-19-57 and 10-3-57, *Doriden tablets*, *Equanil tablets*, and *phenobarbital sodium capsules* were each dispensed twice and *amphetamine sulfate tablets* and *Frenquel hydrochloride tablets* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 6-29-59. \$300 fine, suspended sentence of 1 year in jail, and probation for 2 years.

5693. (F.D.C. No. 41712. S. Nos. 50-696 M, 74-911 M.)

INFORMATION FILED: 5-13-58, Dist. Ariz., against William M. Felsher, t/a Felsher Prescription Pharmacy, Phoenix, Ariz.

CHARGE: Between 3-12-57 and 3-18-57, *Meticorten tablets* were dispensed once upon request for a prescription refill without authorization by a prescriber; and *Aureomycin capsules* were dispensed once without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 3-23-59. \$250 fine and probation for 5 years.

5694. (F.D.C. No. 41713. S. Nos. 74-904/5 M.)

INFORMATION FILED: 5-13-58, Dist. Ariz., against Citrus Drug (a partnership), Phoenix, Ariz., and Edward W. Gibbons (partner).

CHARGE: On 3-15-57, *Nembutal capsules* (count 1) and *Dexedrine Sulfate tablets* (count 2) were each dispensed once upon requests for prescription refills without authorization by a prescriber.

PLEA: Guilty by the partnership to count 1 and by Gibbons to count 2.

DISPOSITION: 3-2-59. Each defendant fined \$100.

5695. (F.D.C. No. 41711. S. Nos. 50-697 M, 51-126 M, 51-131 M, 74-902 M, 74-909 M.)

INFORMATION FILED: 5-13-58, against Henry F. Beckman, t/a Economy Drug, Phoenix, Ariz., and Harold Dwyer (pharmacist).



**CHARGE:** Between 3-12-57 and 3-17-57, *Mysteclin capsules* and *Cortone Acetate tablets* were each dispensed twice upon requests for prescription refills without authorization by a prescriber; and *Meticorten tablets* were dispensed once without a prescription.

**PLEA:** Not guilty by Beckman and Dwyer.

**DISPOSITION:** On 3-10-59, the case was tried before the court without a jury. The defendants were found guilty, and, on 5-4-59, were each fined \$250 and placed on probation for 5 years.

5696. (F.D.C. No. 42035. S. Nos. 41-272 M, 41-284 M, 41-287 M, 80-392 M.)

**INFORMATION FILED:** 3-9-59, Dist. Minn., against Village Drugs, Inc., Newport, Minn., Robert E. North (president and manager), Robert A. North (vice president), and Allen N. Doeltz (pharmacist).

**CHARGE:** Between 12-5-57 and 12-30-57, *pentobarbital sodium capsules* and *Dexedrine Spansule capsules* were each dispensed once upon request for prescription refills without authorization from the prescriber; and *penicillin tablets* and *tablets containing sulfadiazine, sulfamerazine, and sulfamethazine* were each dispensed once without a prescription.

**PLEA:** Guilty by the corporation to all counts; by Robert E. North to the counts involving the *pentobarbital sodium capsules* and *Dexedrine Spansule capsules*; by Robert A. North to the count involving the *penicillin tablets*; and by Doeltz to the count involving the *pentobarbital sodium capsules*.

**DISPOSITION:** 4-27-59. Corporation—\$500 fine; Robert E. North—\$250 fine; Robert A. North and Allen Doeltz—each \$25 fine. Each individual also placed on probation for 3 months.

5697. (F.D.C. No. 40597. S. Nos. 24-293/300 M, 50-601/23 M, 50-642 M, 50-646 M, 51-179/80 M, 51-186/87 M.)

**INDICTMENT FILED:** 3-26-58, S. Dist. Calif., against George E. Fakehany, M.D., David E. Pearl, D.O., and Raymond M. Braddock, D.O., Los Angeles, Calif.

**CHARGE:** The indictment alleged in count I that the defendants willfully and knowingly conspired, combined and agreed together, with each other, and with other persons, to violate 301(k); that it was a part of the conspiracy that prescription drugs such as *amphetamine sulfate tablets*, *pentobarbital sodium capsules*, and *secobarbital sodium capsules* would be dispensed without a prescription while held for sale after shipment in interstate commerce; that such drugs would be repackaged from bulk containers into pill boxes which did not bear the statement "Caution: Federal law prohibits dispensing without prescription"; that such drugs in the pill boxes would be held for ready dispensing; that George E. Fakehany would operate a medical office at 738 North Highland Avenue, Los Angeles, Calif., under such names as Highland Medical Group, Highland Medical Center, and Highland Medical Clinic; that George E. Fakehany would employ at such office, a staff which included David E. Pearl and Raymond M. Braddock; that a pill box containing 50 *amphetamine sulfate tablets* would sell for \$5.00 and a pill box containing 30 *pentobarbital sodium capsules* or *secobarbital sodium capsules* would sell for \$3.00; that a record book would be maintained in which were noted the names of customers who were "O.K." and to whom the drugs in the pill boxes could be sold whenever such customers asked for them; that a new customer could have his name recorded in the record book and thus become eligible to purchase drugs by having an established customer introduce him to one of the defendants as a

friend who wanted the drugs; that when a customer would come to the medical office to buy the drugs, he would be required to make his request known to the receptionist, or to one of the defendants, or to one of the other persons employed at the medical office, to the effect that a customer who wanted *amphetamine sulfate tablets* would say that he wanted "reducers" or "50," and a customer who wanted *pentobarbital sodium capsules* or *secobarbital sodium capsules* would say that he wanted "sleepers" or "30"; that a customer would commonly ask for "reducers and sleepers" or for "50 and 30"; and that the defendants would sell to the customer the drugs requested by the customer, without any medical history, physical examination, or laboratory determination, without ascertaining whether the customer had any bona fide need for such drugs, or whether the use of the drugs might involve danger to the health of the customer, without checking to determine whether the customer was becoming addicted to or dependent upon such drugs, without taking the initiative in suggesting medication, or any course of therapy, and without establishing a bona fide doctor-patient relationship; and, that in pursuance of the conspiracy and to effect the objects thereof, the defendants committed various overt acts including the selling of quantities of *amphetamine sulfate tablets*, *pentobarbital sodium capsules* and *secobarbital sodium capsules* without prescription, at various times between 4-27-55 and 2-23-56.

The indictment alleged also in counts 2-20 that, between 4-11-55 and 3-14-56, *amphetamine sulfate tablets* (counts 2, 4, 5, 7, 8, 10, 11, 12, 14, 16, 18, and 20) were dispensed 12 times, *pentobarbital sodium capsules* (counts 3, 6, 9, 17, and 19) were dispensed 5 times and *secobarbital sodium capsules* (counts 13 and 15) were dispensed twice without a prescription.

PLEA: Not guilty by Fakehany to all counts of the indictment; by Pearl to counts 1, 12, 13, 14 and 15; and by Braddock to counts 1, 8, 9, 10 and 11.

DISPOSITION: The case came on for trial before the court and jury on 8-5-58, and was concluded on 8-21-58, with the return by the jury of a verdict of guilty. On 9-15-58, the court fined Fakehany \$2,000 and Braddock \$500, which fines were suspended. The court also placed Braddock and Pearl on probation for 1 year.

5698. (F.D.C. No. 41727. S. Nos. 65-522 M, 65-524/5 M.)

INFORMATION FILED: 7-8-58, E. Dist. Ky., against Irene Hammonds Garrett, Lexington, Ky.

CHARGE: Between 8-21-57 and 10-7-57, *Dexedrine Sulfate tablets* were dispensed 3 times without a prescription.

PLEA: Not guilty.

DISPOSITION: The case came to trial before a jury on 3-19-59, and was terminated by a verdict of guilty on 3-20-59. On the same day, the court imposed a sentence of 6 months and 10 days in jail.

5699. (F.D.C. No. 41768. S. Nos. 82-261/5 M.)

INFORMATION FILED: 9-23-58, S. Dist. Tex., against Earsel H. Becton, t/a Burbank Pharmacy, Houston, Tex.

CHARGE: Between 11-2-57 and 11-8-57, *prednisone tablets* were dispensed twice, and *thyroid tablets*, *sulfisoxazole tablets*, and *penicillin tablets* were each dispensed once without a prescription.

PLEA: Not guilty.

DISPOSITION: On 2-9-59, the case came to trial before a jury and was terminated by a verdict of guilty. On 2-16-59, the court imposed a \$200 fine, and the defendant was given a 6 month suspended jail sentence and placed on probation for 3 years.

5700. (F.D.C. No. 41753. S. Nos. 53-883/4 M, 53-886/7 M, 53-889 M.)

INFORMATION FILED: 4-22-59, S. Dist. Tex., against Seymour J. Sanov, t/a MacGregor Pharmacy, Houston, Tex.

CHARGE: Between 5-3-57 and 5-9-57, *Equanil tablets* were dispensed twice and *Meticorten tablets*, and *Gantrisin tablets* were each dispensed once without a prescription, and *penicillin tablets* were dispensed once upon request for a prescription refill without authorization from a prescriber.

PLEA: Not guilty.

DISPOSITION: On 7-8-59, the case came to trial before the court without a jury and at the conclusion of the trial the defendant was found guilty. On 7-20-59, the defendant was fined \$250.

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<sup>1</sup> (5695, 5697-5700) Prosecution contested.<sup>2</sup> (5681) Violation of probation.

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<sup>1</sup> (5695, 5697-5700) Prosecution contested.<sup>2</sup> (5680) Prosecution contested. Contains opinion of the court.



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<sup>1</sup> (5695, 5697-5700) Prosecution contested.

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<sup>1</sup> (5695, 5697-5700) Prosecution contested.

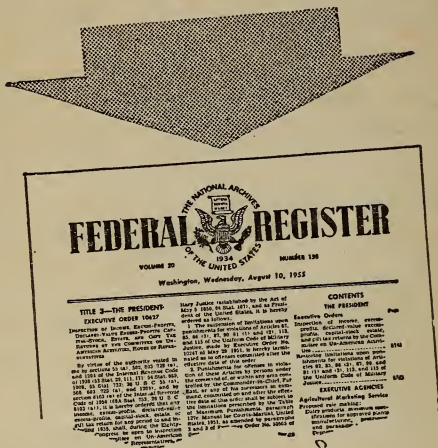
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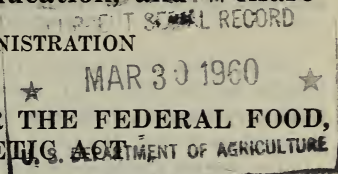


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## U.S. Department of Health, Education, and Welfare

## FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD,  
DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

5701-5740

## DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were adulterated or misbranded within the meaning of the Act when introduced into and while in interstate commerce or while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings in which decrees of condemnation were entered after default or consent; (2) criminal proceedings terminated with a plea of guilty or nolo contendere; and (3) an injunction proceeding terminated with a dismissal after the granting of a temporary restraining order. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation, and the criminal and injunction proceedings are against the *firms* or *individuals* charged to be responsible for violations.

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GEO. P. LARRICK, *Commissioner of Food and Drugs.*

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\*For presence of a habit-forming substance without warning statements, see No. 5707; omission of, or unsatisfactory, ingredient statements, Nos. 5705, 5707, 5709, 5716; an imitation of, and sale under name of, another drug, No. 5705; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 5705, 5707, 5709, 5716; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 5705, 5707, 5716; cosmetic, actionable under the drug provisions of the Act, No. 5712.

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS  
REPORTED IN D.D.N.J. NOS. 5701-5740

*Adulteration*, Section 501(a) (1), the article consisted in part of a filthy substance; Section 501(a) (2), the article had been prepared, packed, or held under insanitary conditions; Section 501(b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia or National Formulary) and its strength differed from, and its quality and purity fell below, the standard set forth in such compendium; and Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength differed from, or its quality fell below, that which it purported or was represented to possess.

*Misbranding*, Section 502(a), the labeling of the article was false and misleading; Section 502(b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; Section 502(d), the article contained a chemical derivative of barbituric acid, and its label failed to bear the name, and quantity or proportion of such derivative; Section 502(e), the article was a drug not designated solely by a name recognized in an official compendium, and its label failed to bear (1) the common or usual name of the drug; and (2) the drug was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient; Section 502(f), the labeling of the article failed to bear (1) adequate directions for use; and (2) adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 502(i) (2), the article was an imitation of another drug; and (3) the article was offered for sale under the name of another drug; Section 502(j), the article was dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof; and Section 503(b) (4), the article was subject to 503(b) (1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription"; and, in another case, the article bore the caution statement quoted above, but the article was not one to which Section 503(b) (1) applies.

*New-drug violation*, Section 505(a), the article was a new drug within the meaning of Section 201(p), which was introduced into interstate commerce, and an application filed pursuant to Section 505(b) was not effective with respect to such drug.

DRUG ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED  
ACCORDING TO DIRECTIONS

5701. Vitamin capsules. (F.D.C. No. 41851. S. No. 35-361 P.)

QUANTITY: 171 btl. at Philadelphia, Pa.

SHIPPED: The capsules were shipped in bulk, on 3-19-58, from Detroit, Mich.

LABEL IN PART: (Btl.) "500 Capsules List No. 100 VITAL B-C THERAPEUTIC FORMULA Each capsule contains 25,000 units of Vitamin A \* \* \* 1 mg. of Vitamin B<sub>1</sub> \* \* \* 5 mg. Ascorbic Acid \* \* \* Prepared for Daniel Cooperman."

**ACCOMPANYING LABELING:** Folder entitled "Directions for the use of Vital B-C Capsules.", reading in part: "Three capsules four times a day before meals and at bedtime."

**RESULTS OF INVESTIGATION:** The capsules in the above-described shipment were, after arrival at Philadelphia, Pa., repackaged into bottles and labeled as described above.

**LIBELED:** 6-4-58, E. Dist. Pa.

**CHARGE:** 502(a)—the labeling of the article, while held for sale, contained false and misleading representations that the article was an adequate and effective treatment for acne; and 502(j)—the article, because of its content of vitamin A, was dangerous to health when used in the dosage, and with the frequency and duration prescribed, recommended, and suggested in its labeling, namely, "Three capsules four times a day before meals and at bedtime," which were the recommended directions contained in the folder entitled "Directions for the use of Vital B-C Capsules."

**DISPOSITION:** 8-29-58. Consent—claimed by Daniel Cooperman Pharmacy, Philadelphia, Pa., and relabeled.

### NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

**5702. Clarimycin (3 seizure actions).** (F.D.C. Nos. 41607, 41608, 41609, 41610, 41677. S. Nos. 8-341 P, 11-763 P, 11-866/7 P, 16-789 P.)

**QUANTITY:** 1,912 display cards, each containing 1 btl., at Highland Park and Detroit, Mich.; 33 display cartons, each containing 6 btl., at Cleveland, Ohio; and 297 btl., at Pittsburgh, Pa.

**SHIPPED:** Between 12-12-57 and 2-24-58, from Jersey City, N.J., by Meritt Corp.

**LABEL IN PART:** (Btl.) "Contents 5 drams Clarimycin Anti-biotic Acne Lotion  
\* \* \* Active Ingredients: Neomycin Sulphate, Allantoin."

**LIBELED:** Between 3-3-58 and 4-23-58, E. Dist. Mich., W. Dist. Pa., and N. Dist. Ohio.

**CHARGE:** 502(a)—when shipped, the labeling of the article in the Cleveland and Pittsburgh lots contained false and misleading representations that the article was an adequate and effective treatment for acne, pimples, blackheads, and stubborn skin infections; and 505(a)—the article, in all lots, was a new drug which may not be introduced into interstate commerce, and an application filed pursuant to law was not effective with respect to such drug.

**DISPOSITION:** Between 8-21-58 and 10-21-58. Consent—destruction.

**5703. Meprobamate tablets.** (F.D.C. No. 41895. S. No. 4-401 P.)

**QUANTITY:** 1 drum containing 25,000 tablets at Richmond, Va.

**SHIPPED:** 5-6-58, from Brooklyn, N.Y., by Hall Pharmacal Co., Inc.

**RESULTS OF INVESTIGATION:** Analysis showed that the article contained approximately 400 milligrams of meprobamate per tablet.

**LIBELED:** 6-27-58, E. Dist. Va.

**CHARGE:** 502(a)—the statement on the drum label "For Investigational and Export Use Only" was false and misleading as applied to the article; and 505(a)—when shipped, the article was a new drug which may not be introduced into interstate commerce, since an application filed pursuant to law was not effective with respect to such drug.



DISPOSITION: 9-8-58. Default—destruction.

**5704. Meprobamate tablets.** (F.D.C. No. 41894. S. Nos. 29-956/7 P.)

QUANTITY: 3 drums containing a total of 512,000 tablets and one drum containing a total of 94,000 tablets at Brooklyn, N.Y.

SHIPPED: A quantity of meprobamate powder was shipped from East Paterson, N.J., and, after its arrival at Brooklyn, N.Y., was tableted and packed into the 3 drums described above. The 1 drum lot was a return shipment which was made on 6-4-58, from Philadelphia, Pa.

LABEL IN PART: (3 drum lot) "2-methyl-2-n-propyl-1, 3-propanediol dicarbamate. For manufacturing, processing, or repacking in the preparation of a new drug limited by Federal law to investigational use. Caution: \* \* \* For Export Only"; (1 drum lot) "100,000 Tablets Meprobamate \* \* \* 400 Mg. \* \* \* Caution \* \* \* Dosage: 1 Tablet 3 times Daily. For investigational and export use only Hall Pharmacal Co., Inc., New York, N.Y."

RESULTS OF INVESTIGATION: Analysis showed that the article (both lots) contained approximately 400 milligrams of meprobamate per tablet.

Investigation showed that the article was not intended for export.

LIBELED: 7-7-58, E. Dist. N.Y.

CHARGE: 502(a)—while held for sale, the statement on the label of the article "For manufacturing, processing, or repacking in the preparation of a new drug limited by Federal law to investigational use \* \* \* For Export Only" was false and misleading; and 505(a)—the article was a new drug, and an application filed pursuant to 505(b) was not effective with respect to such drug.

DISPOSITION: 3-26-59. Consent—destruction.

**5705. Meprobamate tablets and meprobamate powder.** (F.D.C. No. 41764. S. Nos. 62-771 M, 29-942 P.)

INFORMATION FILED: 9-23-58, Dist. N.J., against Abraham J. Schwartz, Jersey City, N.J.

SHIPPED: *Meprobamate tablets* were shipped on 3-26-57, and *meprobamate powder* was shipped on 3-8-57, from New Jersey to New York.

CHARGE: 502(b)—the articles failed to bear labels containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; 502(e) (1)—the labeling of the articles failed to bear the common or usual name of the drug; 502(f) (1)—the labeling of the articles failed to bear adequate directions for use; 502(i)—the *meprobamate tablets* were (2) an imitation of another drug, namely, Miltown, and (3) were offered for sale under the name of another drug, namely, Miltown; and 503(b) (4)—the labeling of the articles failed to bear the statement "Caution: Federal law prohibits dispensing without prescription"; and 505(a)—the *meprobamate tablets* were a new drug, and an application filed pursuant to the law was not effective with respect to the drug.

PLEA: Guilty.

DISPOSITION: 5-22-59. \$1,800 fine and probation for 5 years.

**5706. Vitamin B<sub>12</sub> injection.** (F.D.C. No. 39431. S. No. 52-010 M.)

QUANTITY: 52 vials at Brooklyn, N.Y.

SHIPPED: 5-21-56, from Chicago, Ill., by Medical Chemicals Corp.



**LABEL IN PART:** (Vial) "10 cc Sterile Multiple Dose Vial Injection Cyanocobalamin U.S.P. XV Vitamin B<sub>12</sub> U.S.P. Crystalline 1000 mcg/cc in Isotonic Normal Saline Solution with 1½% of Benzyl Alcohol-Intramuscular Contains no crude cyanocobalamin."

**RESULTS OF INVESTIGATION:** Examination showed that each cubic centimeter of the article contained 1 milligram (=1,000 mcg.) of cyanocobalamin (vitamin B<sub>12</sub>), 8.77 milligrams of sodium chloride, and 0.98 milligram of unidentified dissolved material.

**LIBELED:** 8-22-56, E. Dist. N.Y.

**CHARGE:** 501(b)—when shipped, the quality and purity of the article fell below the standard for *cyanocobalamin injection* set forth in the United States Pharmacopeia since it contained, in each cubic centimeter, dissolved material which was not permitted by the standard as an ingredient of *cyanocobalamin injection*; and 505(a)—the article, because of the presence of unidentified dissolved material, was a new drug within the meaning of 505(b), and an application filed pursuant to the law was not effective.

**DISPOSITION:** Medical Chemicals Corp., claimant, filed an answer denying that the article was a new drug or was adulterated as charged in the libel. The Government filed written interrogatories which the claimant answered in part and objected to in part. Thereafter, the parties having stipulated and agreed on the interrogatories to which answers should be made, the court, on 6-10-57, ordered such interrogatories to be answered.

On 3-25-59, the claimant having represented that the value of the article under seizure was negligible, and that the standard for the article set forth in the United States Pharmacopeia had been clarified to include a specific test for solids which test was not part of the U.S.P. monograph at the time of shipment, and, having consented to the entry of a decree without admitting any of the issues of law and fact involved, judgment of condemnation was entered and the article was ordered destroyed.

## DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS\*

**5707. Various drugs.** (F.D.C. No. 41867. S. Nos. 14-201/5 P, 14-207/11 P, 14-213/5 P, 14-223 P, 14-226 P, 14-228 P, 14-230 P.)

**QUANTITY:** 10 btl. of *Triple-Sulfa No. 1 tablets*; 11 btl. of *Quinidine Sulfate capsules*; 5 btl. of *Quinine Sulfate capsules*; 14 btl. of *stilbestrol tablets*; 6 btl. of *sodium salicylate tablets*; 27 btl. of *sulfadiazine tablets*; 5 btl. of *aminophylline tablets*; 7 btl. of *methyltestosterone sublingual tablets*; 27 btl. of *De-em (dextro-amphetamine sulfate) timed capsules*; 6 btl. of *sulfathiazole tablets*; 5 100-tablet vials and 7 1,000-tablet vials of *thyroid tablets*; 7 btl. of *Neo-Histagen tablets*; 6 btl. of *Theophenyllin tablets*; 22 btl. of *Timcaps (dextro-amphetamine sulfate capsules)*; 10 btl. of *#1 (dextro-amphetamine sulfate with amobarbital) capsules*; and 15 btl. of *#2 (dextro-amphetamine sulfate with amobarbital) capsules*, at Detroit, Mich., in possession of Spartan-Rex Chemical Co.

**SHIPPED:** Between 1-24-57 and 4-9-58, from Philadelphia, Pa., and Norwich, N.Y.

**LABEL IN PART:** (Btl.) "1000 Tablets S-R Triple-Sulfa No. 1 7.5 Grains," "1000 Capsules S-R Quinidine Sulfate," "1000 Capsules S-R Quinine Sulfate,"

\*See also No. 5705.

"1000 Tablets \* \* \* S-R Stilbestrol," "1000 Tablets Sodium Salicylate," "1000 Tablets S-R Sulfadiazine," "1000 Tablets S-R Buff \* \* \* Aminophylline," "1000 Tablets S-R Methyl Testosterone Sublingual," "De-Em Timed Capsules Dextro Amphetamine Sulfate 10 Mgm Dose \* \* \* Donaker Drug Company, Des Moines, Iowa," "100 Sulfathiazole"; (vial) "100 [or 1000] Tablets Thyroid"; (btl.) "100 Tablets Neo-Histagen with S-P Compound," "100 Theophenyllin Tablets," "1000 Capsules TIMCAPS Dextro Amphetamine Sulfate 15 Mgm. \* \* \* Donaker Drug Company, Des Moines, Iowa," "#1" and "#2."

RESULTS OF INVESTIGATION: The articles, with the exception of the 22 btl. lot of *Timcaps* (*dextro-amphetamine sulfate capsules, 15 mgs.*) were repackaged and relabeled by the dealer after their shipment in interstate commerce as described above.

LIBELED: 6-20-58, E. Dist. Mich.

CHARGE: *Triple Sulfa No. 1 tablets, stilbestrol tablets, sulfadiazine tablets, aminophylline tablets, methyltestosterone sublingual tablets, Quinidine Sulfate capsules, Quinine Sulfate capsules, sodium salicylate tablets.* 502(a)—while held for sale, the label statement "1000 Tablets" (or "1000 capsules") was false and misleading as applied to the articles which contained fewer than 1,000 tablets (or capsules) in each bottle; and 502(b) (2)—the articles failed to bear labels containing an accurate statement of the quantity of contents.

*Quinine Sulfate capsules.* 502(f) (1)—while held for sale, the labeling of the article failed to bear adequate directions for use; and 503(b) (4)—the article was a drug not subject to 503(b) (1) and its label bore the statement "Caution: Federal law prohibits dispensing without prescription."

*Sodium salicylate tablets.* 502(f) (2)—while held for sale, the labeling of the article failed to bear adequate warning against misuse by children since its labeling failed to bear a statement warning that the article should be kept out of reach of children.

*De-Em timed capsules (dextro-amphetamine sulfate).* 502(a)—while held for sale, the label statement "Donaker Drug Company, Des Moines, Iowa" was false and misleading since such firm was not the manufacturer, packer, or distributor of the article; and 502(b)—the article failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor and (2) an accurate statement of the quantity of contents.

*Sulfathiazole tablets and thyroid tables.* 502(f) (1)—while held for sale, the labeling of the articles failed to bear adequate directions for use; and 503(b) (4)—the articles were subject to 503(b) (1) and their labels failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

*Neo-Histagen tablets (with S-P Compound).* 502(e) (2)—while held for sale, the label of the article failed to bear the common or usual name of each active ingredient; and 502(f) (1)—the labeling failed to bear adequate directions for use; and 502(f) (2)—the labeling failed to bear adequate warning that the article should be kept out of reach of children.

*Theophenyllin tablets.* 502(d)—while held for sale, the article contained a quantity of phenobarbital, a habit-forming derivative of barbituric acid, and its label failed to bear the name and quantity or proportion of such derivative; and 502(e) (2)—the label of the article failed to bear the common or usual name of each active ingredient.



*Timcaps (dextro-amphetamine sulfate capsules)*. 502(a)—while held for sale, the labeling accompanying the article, namely, the labels to be used in repacking the article, contained a false and misleading statement which represented and suggested that the Donaker Drug Company, Des Moines, Iowa, was the manufacturer of the article.

#1 capsules and #2 capsules. 502(b)—while held for sale, the articles failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor and (2) an accurate statement of the quantity of contents; 502(d)—the articles contained amobarbital, a derivative of barbituric acid, and their labels failed to bear the name and quantity or proportion of such derivative; 502(e) (2)—the labels of the articles failed to bear the common or usual name of each active ingredient; 502(f) (1)—their labeling failed to bear adequate directions for use; and 503(b) (4)—the articles were subject to 503(b) (1) and their labels failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: Spartan-Rex Chemical Co. appeared as claimant for the articles of *Triple-sulfa No. 1 tablets*, *Quinidine Sulfate capsules* (7 btl.), *sulfadiazine tablets*, *methyltestosterone sublingual tablets*, *Timcaps (dextro-amphetamine sulfate capsules*, 15 mgs.) (22 btl.); and having consented to the entry of a decree, judgment of condemnation was entered on 2-6-59 against all of the articles under seizure and the court ordered that the articles claimed by Spartan-Rex Chemical Co. be released under bond for relabeling, and that the remainder of the articles under seizure be delivered to a State hospital.

#### DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS\*

5708. Aspirin tablets. (F.D.C. No. 41700. S. No. 34-029 P.)

QUANTITY: 42 boxes, each containing 12 ctns. of 12 tins each, at Lehighton, Pa.

SHIPPED: 6-28-48, from Memphis, Tenn.

RESULTS OF INVESTIGATION: Examination showed the article to be 5 grain *aspirin tablets* containing 0.55 percent free salicylic acid, whereas, the United States Pharmacopeia permits a maximum of 0.15 percent free salicylic acid per aspirin tablet.

LIBELED: 5-8-58, M. Dist. Pa.

CHARGE: 501(b)—the quality and purity of the article, while held for sale, fell below the standard for *aspirin tablets* set forth in the United States Pharmacopeia since the article contained more than the permitted amount of free salicylic acid; 502(f) (1)—the labeling of the article failed to bear adequate directions for use; and 502(f) (2)—the labeling of the article failed to bear adequate warnings against misuse by children, in that, in lieu of a dosage statement for children under 3 years of age, it did not bear a statement that for the 3 year and under age group a physician should be consulted for dosage, and its label did not bear a statement warning that the product should be kept out of reach of children.

DISPOSITION: 6-13-58. Default—destruction.

\*See also Nos. 5705, 5707.

**5709. Ake-Ese tablets and Mentho He-Lum ointment.** (F.D.C. No. 41564. S. Nos. 6-796 P, 6-798 P.)

**QUANTITY:** 2,000 boxes of *Ake-Ese tablets* and 228 boxes of *Mentho He-Lum ointment* at Plymouth, Mass., in possession of International Drug Co.

**SHIPPED:** In 1952, from Norwich, N.Y.

**LABEL IN PART:** "Blakes \* \* \* Ake-Ese Tablets \* \* \* 30 Tablets \* \* \* Acetanilid  $\frac{1}{2}$  Gr. Magnesium Salicylate and Caffeine Flavored with Methyl Salicylate Synthetic" and "Blakes \* \* \* Mentho He-lum Ointment A safe, soothing skin compound."

**RESULTS OF INVESTIGATION:** The articles were shipped in bulk as described above and subsequently repackaged and labeled by the dealer.

**LIBELED:** 5-16-58, Dist. Mass.

**CHARGE:** *Mentho He-lum ointment.* 502(b) (2)—the label of the article, while held for sale, failed to bear an accurate statement of the quantity of contents; and 502(e) (2)—the label of the article failed to bear the common or usual name of each active ingredient of the article.

*Ake-Ese tablets.* 502(f) (2)—the labeling of the article, while held for sale, failed to bear adequate warnings against unsafe dosage and duration of administration in such manner and form as are necessary for the protection of users since the article contained acetanilid, and the labeling failed to warn that frequent and continued use may cause serious blood disturbances and dependence on the article, and since the article contained salicylates, and its labeling failed to warn that the article should be kept out of reach of children.

**DISPOSITION:** 7-7-58. Default—destruction.

**5710. Gold's Nature Brand tablets.** (F.D.C. No. 41843. S. No. 16-207 P.)

**QUANTITY:** 1,008 100-tablet btls. at Worcester, Mass.

**SHIPPED:** 5-13-58, from Columbus, Ohio. This was a return shipment.

**LABEL IN PART:** "Gold's Nature Brand Tablets \* \* \* As a dietary supplement \* \* \* six tablets contain: Tricalcium Phosphate 400 mg. Nux Vomica 6 mg. (not less than 0.07 mg. of Strychnine) Damiana 6 mg. Passion Flower Extract 300 mg. Vitamin B<sub>1</sub> 30 mg. Niacinamide 120 mg. Dry Ferrous Sulphate 120 mg. Lecithin 150 mg. Vitamin E 1 I.U."

**LIBELED:** 5-27-58, Dist. Mass.

**CHARGE:** 502(f) (1)—the labeling of the article, when shipped, failed to bear adequate directions for use for the purposes for which it was intended.

The article was alleged also to be adulterated under the provisions of the law applicable to foods as reported in notices of judgment on foods, No. 25244.

**DISPOSITION:** 7-17-58. Default—destruction.

**5711. Folix-B tablets with iron.** (F.D.C. No. 41846. S. No. 30-499 P.)

**QUANTITY:** 794 btls. at New York, N.Y.

**SHIPPED:** In September 1950, from Berkeley, Calif.

**LABEL IN PART:** (Btl.) "100 Folix-B Tablets With Iron Each containing: Folic acid 3.3 mgs. Thiamin hydrochloride (B<sub>1</sub>) 3.0 mgs. Riboflavin (B<sub>2</sub>) 6.0 mgs. Niacinamide 30.0 mgs. Pyridoxine hydrochloride (B<sub>6</sub>) 100 micrograms Calcium Pantothenate 1.0 mg. Ferrous gluconate 0.3 gm."

**RESULTS OF INVESTIGATION:** Examination showed that the article contained not more than 34 percent of the labeled amount of vitamin B<sub>1</sub> and not more than 42 percent of the labeled amount of niacinamide.

**LIBELED:** 6-19-58, S. Dist. N.Y.

**CHARGE:** 501(c)—the strength of the article, while held for sale, differed from that which it purported and was represented to possess since the article contained less vitamin B<sub>1</sub> and less niacinamide than declared; 502(a)—the label statement "Each containing \* \* \* Thiamin hydrochloride (B<sub>1</sub>) 3.0 mgs. \* \* \* Niacinamide 30.0 mgs." was false and misleading as applied to a product containing less than the declared amounts of thiamin hydrochloride and niacinamide, and the label statement "Caution: To be dispensed only by or on the prescription of a physician" was false and misleading as applied to a product that was not restricted to dispensing on a physician's prescription; and 502(f) (1)—the labeling of the article failed to bear adequate directions for use since no dosage statement was given and no indications for use were stated.

**DISPOSITION:** 7-18-58. Default—destruction.

**5712. Creme ointment and suntan lotions.** (F.D.C. No. 41902. S. Nos. 1-480/1 P.)

**QUANTITY:** 2,204 ctns. of *creme ointment*, 643 6-oz. btls., and 242 4-oz. btls., and 27 combination sets of *suntan lotions* at Fort Lauderdale, Fla., in possession of Aloe Creme Laboratories, Inc.

**SHIPPED:** 1-29-58, from Milwaukee, Wis., by Kolmar Laboratories, Inc.

**LABEL IN PART:** (Ctn.) "Alo-Creme With Lanolin Ointment \* \* \* Ingredients: Contains 50% or more fresh "gel" from the Aloe Vera leaf, protected in a specially prepared base containing lanolin. Contains no anaesthetic drugs. Distributed by Aloe Creme Laboratories, Inc., Ft. Lauderdale, Florida"; (btl.) "Fashion Tan by Aloe Creme \* \* \* Contains the "gel" of Florida's famous Aloe Vera plant"; (btl.) "After Tan by Aloe Creme \* \* \* contains the "gel" of Florida's famous Aloe Vera Plant in a super rich lanolin base."

**ACCOMPANYING LABELING:** Leaflets entitled "Sunburn vs. Suntan" and "Aloe-Creme Ointment."

**RESULTS OF INVESTIGATION:** The leaflets entitled "Aloe-Creme Ointment" and the ctns. for the ointment were prepared locally.

**LIBELED:** 7-21-58, S. Dist. Fla.

**CHARGE:** 502(a)—while held for sale, the labeling of the ointment contained false and misleading representation that the article was an adequate and effective treatment for all burns, skin abrasions, cuts, rashes, itching, dermatitis, skin irritations, hemorrhoids, piles, and bed sores; and 502(f) (2)—the ointment was offered for piles and hemorrhoids, and its labeling failed to bear a warning that the article should not be used in case of rectal bleeding.

502(a)—when shipped and while held for sale, the labeling which accompanied the suntan lotions contained false and misleading representations that the articles were an adequate and effective treatment for preventing skin cancer.

**DISPOSITION:** 11-18-58. Consent—claimed by Aloe Creme Laboratories, Inc., and relabeled.

**5713. Medicated cream, inhalant and rubbing oil, and castile soap.** (F.D.C. No. 41849. S. Nos. 19-177/9 P.)



QUANTITY: 216 1¼-oz. jars and 17 4-oz. jars of *medicated cream*, 72 1-oz. btl. of *inhalant and rubbing oil*, and 528 pkgs. of *castile soap* at Denver, Colo., in possession of Charles Van Castle.

SHIPPED: 4-29-58, from Tulsa, Okla.

LABEL IN PART: "Smiling-Feet A Truly Wonderful Medicated Cream with Many Uses, Especially for the Feet. Contains Eucalyptus, Peppermint, Thymol, Menthol, Camphor, Phenol, Lanolin, Glycerine, Salicylic and Benzoic Acid in a Special Cream Base," "Smiling Brand Inhalant & Rubbing Oil \* \* \* Active Ingredients Eucalyptus Oil, Menthol, \* \* \* Peppermint Oil, Thymol, Camphor," and "Sanitary Castile Soap for the Complexion, Skin, Scalp and Toilet."

LIBELED: 6-4-58, Dist. Colo.

CHARGE: 502(f) (1)—The labeling of the articles failed to bear adequate directions for use for the purposes for which they were intended, namely, (*medicated cream*) in the treatment of corns, callouses, bunions, cramps, athlete's foot, any kind of skin trouble or skin disease, blackheads, whiteheads, nervous rash, lines in the face, and pimpled skin, (*inhalant and rubbing oil*) in the treatment of weak eyes or poor vision, sinus trouble, arthritis, and rheumatism, and (*castile soap*) for the prevention of greying hair, falling hair, and baldness, which were the purposes for which the articles were offered orally by Charles Van Castle on 5-5-58 and 5-8-58.

DISPOSITION: 7-29-58. Default—the castile soap was delivered to a Federal institution for its use, and the other articles were destroyed.

**5714. Douche solution.** (F.D.C. No. 41785. S. No. 39-625 P.)

QUANTITY: 578 btl. at Sacramento, Calif.

SHIPPED: 3-1-57, from Norwood Heights, Ohio.

LABEL IN PART: "Feminette A Cleansing, Bacteriostatic Douche Especially Designed to Relieve the Itching and Burning Common in Many Types of Vaginitis, Directions \* \* \* Contains: High Molecular Alkyl Dimethyl Benzyl Ammonium Chloride and Aromatics \* \* \* 8 Fl. Oz."

ACCOMPANYING LABELING: Leaflets entitled "Feminette Douche Solution Is For You."

LIBELED: 5-28-58, N. Dist. Calif.

CHARGE: 502(a)—the labeling of the article, while held for sale, contained false and misleading representations that the article was effective for the relief of itching and burning common in many types of vaginitis; and 502(f) (2)—the labeling of the article failed to warn that the article should not be used more than twice weekly unless directed by a physician.

DISPOSITION: 7-16-58. Default—destruction.

**5715. Royal jelly capsules.** (F.D.C. No. 41918. S. No. 19-785 P.)

QUANTITY: 12 btl. at Perry, Okla., in possession of Monte L. Jones Drug Co.

SHIPPED: 5-16-58 and 5-25-58, from Hollywood, Fla.

LABEL IN PART: "48 Capsules Royal Jelly High Potency 50 mg. \* \* \* Each Capsule contains: 50 mg. Royal Jelly, in a base of wheat germ oil, plus other vegetable oils."

ACCOMPANYING LABELING: A newspaper advertisement which had been printed and circulated in Perry, Okla., and which contained representations concerning the efficacy of royal jelly.

**RESULTS OF INVESTIGATION:** The above-mentioned advertisement was printed at the request of and paid for by Monte L. Jones Drug Co. A copy of the advertisement was in the possession of such company and was stored in the drawer containing the stock of *royal jelly capsules*.

**LIBELED:** 7-8-58, W. Dist. Okla.

**CHARGE:** 502(a)—the labeling accompanying the article, while held for sale, namely, the above-mentioned copy of the newspaper advertisement, contained false and misleading representations that the article was an adequate and effective treatment for rejuvenating faulty or worn-out glands, for producing a feeling of youthfulness, producing a general state of well-being, eliminating chronic tiredness, permitting prolonged intellectual work without tiring, giving fast, effective relief to women during critical years, and for ulcers; and 502(f) (1)—the labeling of the article failed to bear adequate directions for use for the purposes for which it was intended, namely, the conditions and purposes mentioned in the above-mentioned newspaper advertisement.

**DISPOSITION:** 8-11-58. Default—destruction.

**5716. First aid kits.** (F.D.C. No. 41855. S. No. 31-495 P.)

**QUANTITY:** 143 *first aid kits* at New York, N.Y.

**SHIPPED:** On various dates during the two years prior to 2-13-57, from St. Louis, Mo.

**RESULTS OF INVESTIGATION:** Examination showed that the article was a canvas strip consisting of 3 pouches containing 1 bandage dressing and an iodine applicator, 1 bottle of Frazer's Solution, 6 "Band-Aid" strips, 1 card of safety pins, 1 roll of rubberized material for wrapping sprains, 2 tubes of boric acid, and 3 applicator bottles of tincture of iodine or 2 tubes of petrolatum. The Frazer's Solution showed the quantity of contents to be 71 percent of the amount declared on the label, and the bottles were abnormal because of corrosion and leakage. The kit container failed to declare the contents, the bandage dressing was unlabeled, the roll of rubberized wrapping did not bear directions for use, and the boric acid carton declared the presence of seasickness preventive which was not present.

**LIBELED:** 7-14-58, S. Dist. N.Y.

**CHARGE:** 501(c)—the quality of the Frazer's Solution, while held for sale, fell below that which it purported and was represented to possess since the bottles were abnormal because of corrosion and leakage; 502(a)—the label of the Frazer's Solution which declared the quantity of contents to be 1 oz. was false and misleading since the bottles of such article contained less than 1 oz.; 502(a)—the carton label of the boric acid was false and misleading since it declared the presence of seasickness preventive which was not included; 502(b)—the label on the canvas kit container and the bandage dressing did not bear (1) the name and place of business of the manufacturer, packer, or distributor, and (2) a statement of the quantity of contents; 502(e) (2)—the canvas kit container failed to bear a label containing the common or usual name of the active ingredients present in the kit components; and 502(f) (1)—the labeling of the bandage dressing and the roll of rubberized wrapping failed to bear adequate directions for use.

**DISPOSITION:** 8-6-58. Default—destruction.

**5717. Niagara Thermo-Cyclopad Home Unit.** (F.D.C. No. 41478. S. No. 15-673 P.)

QUANTITY: 5 devices at Toledo, Ohio.

SHIPPED: Between 11-25-57 and 1-23-58, from Adamsville, Pa.

RESULTS OF INVESTIGATION: The home unit was composed of a kit consisting of a Thermo-Cyclopad with a motor having Cyclo-Massage action, contained in a heating pad of foam rubber which held a heating coil, with a control box; also a hand massage unit with a control box.

LIBELED: 3-21-58, N. Dist. Ohio.

CHARGE: 502(f) (1)—the labeling of the article, while held for sale, failed to bear adequate directions for use in the treatment of polio, polyneuritis, paralytic stroke, paralysis caused by spinal injury, prevention of ulcerated teeth, prevention and treatment of colds and sinus trouble, treatment of muscular dystrophy, multiple sclerosis, crippling arthritis, baldness, stomach ulcers, and influenza, which were the diseases and conditions for which the device was offered in oral advertising at Toledo, Ohio, on February 12, 1958, by Mrs. Ruth Mitchell, a saleswoman for General Home Service, Inc., trading as Niagara of Toledo.

DISPOSITION: 5-26-58. Default—delivered to Food and Drug Administration.

### DRUGS ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

#### 5718. Vegetable oils. (Inj. No. 312.)

COMPLAINT FOR INJUNCTION FILED: 5-14-57, S. Dist. Calif., against Strathmore Oils & Fats Co., Inc., Strathmore, Calif., Malaga Oil Products Div. of Leghorn Trading Co., Inc., Lindsay, Calif., Georges Valabregue, president and general manager of Strathmore, and James B. Fowler, vice-president and general manager of the Lindsay plant of Malaga. Amended complaint filed 9-7-57.

CHARGE: The original complaint alleged that the defendants were engaged in the business of manufacturing, preparing, and distributing oils for edible and medicinal purposes; and, that the defendants had been and were, at the time of filing the complaint, introducing and causing to be introduced, and delivering and causing to be delivered for introduction into interstate commerce, said oils which were adulterated within the meaning of 501(a) (1) and 501(a) (2).

The complaint alleged also that the oils were adulterated under the provisions of the law applicable to foods, as reported in notices of judgment on foods, No. 24741.

The original complaint alleged that the raw materials involved, namely, olive pomace, sesame seed, walnut oil stock, almond oil stock, and other by-product materials, were purchased from various food processors for use in the manufacture of the oils and were delivered to the Strathmore plant of defendant, Strathmore Oils & Fats Co., Inc.; that, upon receipt, the raw materials were stored under insanitary conditions at the Strathmore plant; that the contaminated raw materials were subsequently dried and put through a solvent extraction process to remove the oils in such raw materials; that the oils so extracted were placed in storage tanks at the Strathmore plant and held there until they were delivered to the Lindsay plant of the Malaga Oil Products Division; and, that upon delivery to the Lindsay plant, the oils were subjected to a refining process after which they were shipped in interstate commerce.



For a description of the insanitary conditions at the Strathmore plant, see the above-mentioned notice of judgment on foods, No. 24741.

The amended complaint alleged that the olive pomace was purchased by Strathmore from olive pressors and consisted of the residue remaining after olive oil was pressed from olives; that the olive pomace was handled as garbage by the olive pressors and exposed to the elements and to insects, birds, rodents, and squirrels; and, that the olive pomace was adulterated when it reached Strathmore by reason of such exposure.

**DISPOSITION:** On 5-14-57, the court issued a temporary restraining order restraining the defendants from shipping or causing the shipment in interstate commerce, and, more particularly, from delivering or causing the delivery to persons in California known to be engaged in the distribution of oils in interstate commerce, oils which consisted in part of filthy substances or had been prepared or held under insanitary conditions.

On 10-29-57, the cause came on for a hearing on the motion for a preliminary injunction. Thereafter, on 11-6-57, the court orally denied the motion.

Subsequently, on 2-11-58, the Government filed a motion to dismiss the complaint, based upon the grounds that (1) there had been a material improvement in the operations of Strathmore Oils & Fats Co., Inc., especially in the handling of raw materials and extracted oils; (2) that the temporary restraining order had resulted in the adoption by the defendants of a sanitation program encompassing the suppliers of raw materials; and (3) that there appeared to be no further need for an injunction to prevent violation of the Act. The motion to dismiss was granted by the court on 2-12-58.

#### **DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS\***

**5719. Chorionic gonadotropin.** (F.D.C. No. 41317. S. No. 68-044 M.)

**QUANTITY:** 180 vials at Kansas City, Mo.

**SHIPPED:** 4-25-57, from Los Angeles, Calif.

**LIBELED:** 1-6-58, W. Dist. Mo.

**CHARGE:** 501(c)—while held for sale, the strength of the article differed from that which it was represented to possess, namely, 10,000 I.U. of *chorionic gonadotropin* potency per vial; and 502(a)—the label statement "10,000 Int. Units Chorionic Gonadotropin" was false and misleading as applied to a product, the potency of which was substantially less than 10,000 I.U. of *chorionic gonadotropin*.

**DISPOSITION:** 2-25-58. Default—destruction.

**5720. Chorionic gonadotropin.** F.D.C. No. 41358. S. No. 86-963 M.)

**QUANTITY:** 969 vials at Kansas City, Mo.

**SHIPPED:** 9-26-57 and 10-16-57, from Orange, N.J.

**RESULTS OF INVESTIGATION:** Examination showed that the article contained substantially less than 2,500 I.U. of *chorionic gonadotropin* potency per vial.

**LIBELED:** On or about 1-16-58, W. Dist. Mo.

**CHARGE:** 501(c)—while held for sale, the strength of the article differed from that which it was represented to possess, namely, 2,500 I.U. of *chorionic gonadotropin* potency per vial.

\*See also Nos. 5706, 5708, 5711, 5716.

DISPOSITION: 2-26-58. Default—destruction.

**5721. Arben capsules.** (F.D.C. No. 40615. S. No. 65-351 M.)

INFORMATION FILED: 8-4-58, S. Dist. Fla., against Arthur Bennett, Miami Beach, Fla.

SHIPPED: 12-31-56, from Miami Beach, Fla., to Youngstown, Ohio.

LABEL IN PART: "Arben Capsules Number 2 Each capsule contains: Desiccated Thyroid 5 mgm. Caffeine 2.2 mgm. Amphetamine Sulfate 1.2 mgm. With fillers Arthur Bennett Pharmaceuticals Miami Beach, Florida #1109."

CHARGE: 501(c)—the strength of the article differed from that which it purported to possess since each capsule of the article contained more than 1.2 milligrams of amphetamine sulfate.

PLEA: Nolo contendere.

DISPOSITION: 2-25-59. \$1,000 fine.

**5722. Del-Bardex capsules.** (F.D.C. No. 41692. S. No. 39-322 P.)

QUANTITY: 1 drum containing 9,600 capsules at Napa, Calif.

SHIPPED: 3-12-58, from Rensselaer, N.Y., by Delmar Pharmacal Corp.

LABEL IN PART: "Del-Bardex #1 Timed Disintegration Capsule Each Capsule Contains: Dextro Amphetamine Sulfate 10 mg. Amobarbital 60 Mg. \* \* \* Each Capsule Contains 15 Mg. of Dextro Amphetamine Sulfate and 60 Mg. of Amobarbital In a Special Base That Provides for the Disintegration of the Contents Throughout a Period of About 6-10 Hours."

RESULTS OF INVESTIGATION: Analysis showed that the article contained 10 milligrams of dextro-amphetamine sulfate of which 70 percent was released in 2 hours.

FILED: 5-6-58, N. Dist. Calif.

CHARGE: 501(c)—the quality of the article, when shipped, differed from that which it purported or was represented to possess in that it failed to disintegrate at a uniform rate over a 6-10 hour period; and 502(a)—the label statement "Each Capsule Contains 15 Mg. of Dextro Amphetamine Sulfate \* \* \* In a Special Base That Provides for the Disintegration of the Contents Throughout a Period of About 6-10 Hours" was false and misleading as applied to the article which contained only 10 milligrams of dextro-amphetamine sulfate per capsule, and did not release such ingredient at a uniform rate over a 6-10 hour period.

DISPOSITION: 6-12-58. Default—destruction.

**5723. Somnesium capsules.** (F.D.C. No. 41861. S. No. 31-358 P.)

QUANTITY: 326 24-capsule vials at Newark, N.J., in possession of Hicks Pharmacal Co.

SHIPPED: 9-25-57, from Mount Vernon, N.Y.

LABEL IN PART: "Somnesium to induce Sleep Each capsule contains 25 mg. Methapyrilene HCl. 66.6 mg. Aspirin 133.4 mg. Salicylamide \* \* \* Distributed by Hicks Pharmacal Company."

RESULTS OF INVESTIGATION: Examination showed that the product had the odor of acetic acid, a caking of the contents, free salicylic acid, and 70 percent of the labeled amount of aspirin, all of which indicated decomposition of the aspirin. The article contained the labeled amount of methapyrilene HCl and salicylamide.

The article was repacked locally for the dealer from bulk stock shipped as described above.

**LIBELED:** 6-11-58, Dist. N.J.

**CHARGE:** 501(c)—while held for sale, the strength of the article differed from, and its purity and quality fell below, that which it purported and was represented to possess; and 502(a)—the label statement "Each capsule contains \* \* \* 66.6 mg. Aspirin" was false and misleading.

**DISPOSITION:** 7-14-58. Default—destruction.

**5724. Nibromiphen tablets.** (F.D.C. No. 41886. S. No. 8-968 P.)

**QUANTITY:** 3 bulk drums, each containing 31,600 tablets, and 1 btl. containing 1,000 tablets at Rochester, N.Y., in possession of Groh Co.

**SHIPPED:** 11-11-54, from Cleveland, Ohio.

**LABEL IN PART:** (Drum) "Special Tablets Lt. Blue Enteric." and (btl.) "Nibromiphen Enteric Coated Tablets."

**RESULTS OF INVESTIGATION:** The tablets in the bottle had been repackaged by the consignee from the above-described bulk drums.

**LIBELED:** 6-25-58, W. Dist. N.Y.

**CHARGE:** 501(c)—while held for sale, the quality of the article fell below that which it purported and was represented to possess since it was represented as enteric-coated tablets, and the enteric coating was split and falling off, and the tablets were discolored and stuck together in clumps.

**DISPOSITION:** 8-1-58. Default—destruction.

**5725. Sulfobromophthalein sodium injection.** (F.D.C. No. 41775. S. Nos. 15-405 P, 16-416 P.)

**QUANTITY:** 5 ctns. containing a total of 435 ampules at Toledo, Ohio.

**SHIPPED:** 2-14-58, from New York, N.Y., by Vitarine Co., Inc.

**LABEL IN PART:** (Ampule) "3 cc. No. 692 Sulfobromophthalein Sodium Injection U.S.P. 50 mg. Per cc. Intravenous Control No. 7566."

**RESULTS OF INVESTIGATION:** Examination showed that the article contained an excessive amount of pyrogen and failed to comply with the pyrogen test of the United States Pharmacopeia.

**LIBELED:** 5-23-58, N. Dist. Ohio.

**CHARGE:** 501(b)—the article purported to be a drug, sulfobromophthalein, the name of which is recognized in the United States Pharmacopeia, an official compendium, and, when shipped, its quality and purity fell below that required by the Pharmacopeia.

**DISPOSITION:** 8-21-58. Default—destruction.

**5726. Beef, iron, and wine preparation.** (F.D.C. No. 42073. S. No. 38-403 P.)

**QUANTITY:** 56 btls. at Texarkana, Ark.

**SHIPPED:** 2-4-58, from St. Louis, Mo., by Allan & Co.

**LABEL IN PART:** "One Pint Allan's Beef, Iron and Wine."

**RESULTS OF INVESTIGATION:** Examination showed that the article contained significantly less iron and ammonium citrate than the amount specified in the National Formulary for "Beef, Iron and Wine."

**LIBELED:** 8-1-58, W. Dist. Ark.



CHARGE: 501(b)—the strength of the article, when shipped, differed from the standard set forth in the National Formulary for "Beef, Iron and Wine."

DISPOSITION: 9-17-58. Default—destruction.

**5727. Adhesive bandages.** (F.D.C. No. 41917. S. No. 35-341 P.)

QUANTITY: 240 boxes, each containing 100 individually wrapped *adhesive bandages*, at Chester, Pa.

SHIPPED: 5-13-58, from New Rochelle, N.Y., by Hampton Mfg. Co.

LABEL IN PART: (Box) "100  $\frac{3}{4}$ " x 3" BLUE CROSS Plastic adhesive Bandages Sterile \* \* \* Waterproof \* \* \* Sulfathiazole Pads."

LIBELED: 7-8-58, E. Dist. Pa.

CHARGE: 501(b)—The purity and quality of the article, when shipped, fell below the standard for "Adhesive Absorbent Bandage" set forth in the United States Pharmacopeia since the article was not sterile but was contaminated with living micro-organisms; and 502(a)—the label statement "Sterile" was false and misleading.

DISPOSITION: 8-13-58. Default—destruction.

**5728. Clinical thermometers.** (F.D.C. No. 42044. S. No. 38-396 P.)

QUANTITY: 103 *clinical thermometers* at El Dorado, Ark.

SHIPPED: 5-7-58, from Brooklyn, N.Y., by Fulton Thermometer Co.

LABEL IN PART: "Fulton Fever Thermometer."

RESULTS OF INVESTIGATION: Examination of 24 thermometers revealed that 4 thermometers failed to meet the labeled standard of accuracy, and that 24 failed to meet the pigmentation retention tests set forth in Commercial Standards CS 1-52.

LIBELED: 7-8-58, W. Dist. Ark.

CHARGE: 501(c)—the quality of the article, when shipped, fell below that which it purported and was represented to possess; and 502(a)—the following statement in the labeling of the article was false and misleading; "This certifies that this Fulton Fever Thermometer has been examined and tested and is correct within plus or minus  $2/10^{\circ}$  at  $98^{\circ}$  and  $102^{\circ}$  F. and  $3/10^{\circ}$  F. at  $106^{\circ}$  F. or its equivalent in centigrade scale."

DISPOSITION: 8-26-58. Default—destruction.

**DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MIS-LEADING CLAIMS\***

**5729. Royal jelly capsules.** (F.D.C. No. 41460. S. No. 79-242 M.)

QUANTITY: 412 ctns., each containing 1 plastic tube holding 15 capsules, at New York, N.Y.

SHIPPED: Between 3-26-57 and 6-23-57, by Miel Carlota S.A., "Santa Fe" Orchard, 79 Chapultepec Ave., Cuernavaca, Morelos, Mexico.

LABEL IN PART: (Ctn.) "Jalea Real Royal Jelly Miel Carlota, S. A. Miel Carlota Has Obtained This Royal Jelly From Selected Queen Cells Not Older Than 24 Hours After Introducing The Larvae, Which gives the Most Active Concentration. The Harvest of Royal Jelly is Under Constant Scientific and Medical Control of our Doctor Hans Joachim Speck. Royal Jelly in Capsules Has Stablized its Activity by Our Doctor Hector Lopez Arista, According to

\*See also Nos. 5701-5704, 5707, 5711, 5712, 5714-5716, 5719, 5722, 5727, and 5728.

a Special Process. \* \* \* 15 Capsules of 30 Milligrams each" and (tubes) "Jalea Real de Miel Carlota S. A. Serie III."

ACCOMPANYING LABELING: Leaflets reading in part "His Holiness, Pope Pius XII after the recuperation from his grave illness."

LIBELED: 3-27-58, S. Dist. N.Y.

CHARGE: 502(a)—the labeling of the article, when shipped, contained false and misleading representations that the article had extraordinary medical activity and that it was effective for overcoming grave illness, providing extraordinary recovery from serious illness, and providing a magnificent condition of health in persons of advanced age.

DISPOSITION: 7-7-58. Default—destruction.

**5730. Royal jelly tablets.** (F.D.C. No. 41653. S. No. 40-783 P.)

QUANTITY: 7 vials at Great Falls, Mont.

SHIPPED: 1-21-58, from Hollywood, Calif., by Charm Cosmetics.

LABEL IN PART: "Zim Queen Bee Royal Jelly Tablets, Net Contents 50 Tablets, Each Tablet Provides Queen Bee Royal Jelly 25 Mg. Containing Natural Vitamins, Minerals and Iron in Excess to List Below, Lot No. 20461."

ACCOMPANYING LABELING: Window signs and bag stuffers reading "Add Zim to Your Life"; circulars entitled "Is This Miracle Food of Nature"; and leaflets entitled "Notice from Charm Cosmetics to the Dealer" and "To the Wholesaler."

LIBELED: 4-7-58, Dist. Mont.

CHARGE: 502(a)—the labeling accompanying the article, when shipped, contained false and misleading representations that the article would give one added vim, vigor, and vitality, overcome depression, balance the system, cure many glandular and nervous disorders, stimulate the appetite, lengthen life, increase sexual drive, and give one a feeling of general well-being.

DISPOSITION: 6-11-58. Default—destruction.

**5731. Ulca-tone.** (F.D.C. No. 41563. S. No. 2-291 P.)

QUANTITY: 453 btls. at Chattanooga, Tenn.

SHIPPED: Between 4-4-58 and 4-18-58, from Greer, S.C., by Libby, Edwards & Brown, Inc.

LABEL IN PART: "Ulca-Tone 16 Oz. \* \* \* Each Fluid Ounce Contains Aluminum Oxide 26.3 Gr. \* \* \* Magnesium Oxide 5.00 Gr. Hyoscyamine Hydrobromide 0.307 Mg. Hyoscyne Hydrobromide 0.019 Mg. Atropine Sulfate 0.057 Mg. \* \* \* Sole Distributor Dixie Chem. Co. Chattanooga, Tenn."

ACCOMPANYING LABELING: Circulars reading in part "Do You Suffer With Ulcerated Stomach Condition \* \* \* Ulca-Tone Don't Suffer With Stomach Trouble Any Longer!"

LIBELED: 5-16-58, E. Dist. Tenn.

CHARGE: 502(a)—the bottle label and the circular accompanying the article, when shipped, contained false and misleading representations that the article was an adequate and effective treatment for ulcerated stomach and stomach trouble.

DISPOSITION: 7-2-58. Default—destruction.

**5732. Cherefresh (cherry juice).** (F.D.C. No. 43150. S. No. 55-670 P.)

QUANTITY: 16 cases, 12 46-oz. cans each, and 178 cases, 24 12-oz. cans each, at Oklahoma City, Okla.

SHIPPED: 9-27-58 and 10-22-58, from Sturgeon Bay, Wis., by Reynolds Bros., Inc.

LABEL IN PART: (Can) "Cherefresh The Original Refreshing Cherry Drink \* \* \* Reynolds Brothers, Inc., Sturgeon Bay, Wisconsin" or "Cherefresh \* \* \* Cherry Juice."

ACCOMPANYING LABELING: Leaflets entitled: "Arthritis Victims Ask for Cherry Information."

LIBELED: 5-21-59, W. Dist. Okla.

CHARGE: 502(a)—when shipped, the labeling which accompanied the article contained false and misleading representations that the article was an adequate and effective treatment for arthritis, gout, and related ailments.

DISPOSITION: 7-21-59. Consent—claimed by Reynolds Brothers, Inc., and relabeled.

**5733. Darcopherol tablets.** (F.D.C. No. 41892. S. No. 14-394 P.)

QUANTITY: 39 50 tablet btls. and 1 180 tablet btl. at Chicago, Ill.

SHIPPED: Between 3-10-58 and 4-21-58, from Los Angeles, Calif., by Dartell Laboratories.

LABEL IN PART: "Net Contents \* \* \* DPS Formula 7 Darcopherol \* \* \* A dietary Food Supplement Providing Total Vitamin E from natural vegetable oils B Complex Factors Vitamin B-12 Vitamin B<sub>1</sub> Choline Vitamin B-2 Natural Iodine from Sea Vegetation Fatty Unsaturates from Wheat Germ and Soya Bean Dartrate Concentrate."

ACCOMPANYING LABELING: Pamphlets entitled "The Facts About Vitamin E."

LIBELED: 6-26-58, N. Dist. Ill.

CHARGE: 502(a)—the labeling accompanying the article, when shipped, contained false and misleading representations that the article had nutritional properties which would prevent and correct heart disease, diabetes, muscular dystrophy, liver disorders, kidney disease, atherosclerosis and arteriosclerosis, sterility and many other disorders.

DISPOSITION: 7-25-58. Default—destruction.

**5734. DPS Formula Lipotrate tablets.** (F.D.C. No. 41842. S. No. 32-449 P.)

QUANTITY: 8 cases, 12 btls. each, at Philadelphia, Pa.

SHIPPED: 1-8-58 and 4-4-58, from Los Angeles, Calif., by Dartell Laboratories.

LABEL IN PART: (Btl) "DPS Balanced Formulae \* \* \* Formula 4 Lipotrate Net Contents 120 tablets A dietary Food Supplement providing Lipotropic Factors Choline Bitartrate Inositol Betaine dl-Methionine with B-Complex Vitamins Vitamin B-12 Vitamin B-6 Folic Acid Calcium Pantothenate and Minerals Iodine Calcium Phosphorus and containing Dartrate Concentrate."

ACCOMPANYING LABELING: Pamphlet entitled "From Nature Through Experimentation and Research comes Discovery \* \* \* Lipotrate."

LIBELED: 5-27-58, E. Dist. Pa.



CHARGE: 502(a)—the labeling accompanying the article, when shipped, contained false and misleading representations that the article was an adequate and effective treatment for the prevention and correction of jaundice, cirrhosis of the liver, atherosclerosis and diabetes mellitus.

DISPOSITION: 8-27-58. Default—destruction.

5735. Sugar-chek (urine sugar test tape). (F.D.C. No. 41901. S. Nos. 12-980 P, 14-601 P.)

QUANTITY: 385 ctns., each containing 144 retail ctns., at Elgin, Ill.

SHIPPED: 1-25-57 and 2-4-57, from St. Louis, Mo.

LABEL IN PART: "Sugar-Chek \* \* \* (Urine Sugar Test Tape) A specific test for urine glucose (sugar)."

ACCOMPANYING LABELING: (Leaflet in ctn.) "What is a Diabetic."

RESULTS OF INVESTIGATION: Examination showed that the article, while held for sale, was not effective for detecting small amounts of sugar in the urine as claimed in its labeling.

LIBELED: 6-30-58, N. Dist. Ill.

CHARGE: 502(a)—the labeling of the article, while held for sale, contained false and misleading representations that the article was effective for detecting the presence of sugar in the urine and thus acting as a diagnostic sign of diabetes.

DISPOSITION: 7-25-58. Default—destruction.

5736. Slenda-Matic devices. (F.D.C. No. 41794. S. Nos. 25-239 P, 26-551 P.)

QUANTITY: 36 rectangular *Slenda-Matic devices* and 12 contour *Slenda-Matic devices* at Minneapolis, Minn.

SHIPPED: 5-7-58, from Chicago, Ill., by Grayline Co.

LABEL IN PART: (Ctn.) "Rectangular Holco Slenda-Matic Distributed By S. S. Hollender, Inc., Chicago, Illinois" and "Contour Holco Slenda-Matic"; (metal plate on each device) "Slenda-Matic Manufactured by Grayline Company, Chicago 33, Illinois \* \* \* Serial No."

ACCOMPANYING LABELING: Leaflet entitled "Holco Slenda-Matic Vibrating Machine."

RESULTS OF INVESTIGATION: The labeling indicated that each device was a wooden frame box upholstered with polyurethane foam and covered with vinyl material, and that a rheostat-control electric motor providing vibration was enclosed in each box.

LIBELED: 6-4-58, Dist. Minn.

CHARGE: 502(a)—the labeling of the devices, when shipped, contained false and misleading representations that the devices were capable of providing an adequate and effective treatment for improving circulation, easing tensions, reducing weight, regaining a firm, trim, slender figure and removing fatty tissues.

DISPOSITION: 7-22-58. Consent—claimed by E. B. Meyrowitz, Inc., St. Paul, Minn., and relabeled.

5737. Ozone generator. (F.D.C. No. 41454. S. No. 41-302 P.)

QUANTITY: 11 devices at Seattle, Wash.

SHIPPED: 10-21-57, from Germany.

LABEL IN PART: "ELT Mod. TOS-1 \* \* \* Made in Germany."

ACCOMPANYING LABELING: Leaflets entitled "Health Promoting Ozonator" and "Atme Dich Gesund."

RESULTS OF INVESTIGATION: Each device consisted of a horizontally mounted mercury-containing glass tube, completely enclosed and covered with a protective plastic shield.

LIBELED: 3-4-58, W. Dist. Wash.

CHARGE: 502(a)—the labeling accompanying the devices, while held for sale, contained false and misleading representations that the devices were effective for overcoming coughs, headache, whooping cough, tuberculosis, bronchitis, diseases of respiratory organs, rickets, and metabolic disturbances, and for promoting health.

DISPOSITION: 7-14-58. Default—destruction.

**5738. Relax-Or cushion.** (F.D.C. No. 41817. S. No. 26-558 P.)

QUANTITY: 137 devices at Minneapolis, Minn., in possession of John W. Thomas Co.

SHIPPED: 5-7-58, from New York, N.Y.

ACCOMPANYING LABELING: Newspaper tearsheets reading in part "Save While You Slim Relax Away Tensions Pains and Inches With Our 'Vibra' Pillow."

RESULTS OF INVESTIGATION: The newspaper tearsheets were used by the consignee with a counter display of the devices. The device appeared to be an upholstered cushion containing an electric motor providing vibration.

LIBELED: 6-23-58, Dist. Minn.

CHARGE: 502(a)—the labeling accompanying the article, while held for sale, contained false and misleading representations that the article was an adequate and effective treatment for relaxing away tensions, pains, and inches, easing nervous tension instantly, trimming the body, and reducing weight.

DISPOSITION: 7-10-58. Consent—claimed by John W. Thomas Co. and relabeled.

**5739. Electric massage pillows.** (F.D.C. No. 41913. S. Nos. 25-944/6 P.)

QUANTITY: 13 *electric massage pillows*, 11 *Travel-Mate electric massage pillows*, and 7 *Vibra-Therm electric massage and heat pillows* at Waterloo, Iowa.

SHIPPED: 5-14-58, from Chicago, Ill., by Edson, Inc.

LABEL IN PART: (Ctn.) "SLIM-TRIM Electric Massage Pillow", "Slim-Trim Travel-Mate Electric Massage Pillow"; "Slim-Trim Vibra-Therm Electric Massage and Heat Pillow."

ACCOMPANYING LABELING: Leaflets in ctn. entitled "Slim-Trim Electric Massage Pillow How to use and enjoy it," "How to use and enjoy your new Slim-Trim Travel-Mate Electric Massage Pillow," "Slim-Trim Vibra-Therm Electric Massage and Heat Pillow How to use it for best results."

RESULTS OF INVESTIGATION: The articles (all models) consisted of an upholstered cushion containing an electric motor providing vibration, and the Vibra-Therm pillows also contained a dial control switch for heat.

LIBELED: 7-8-58, N. Dist. Iowa.

**CHARGE:** 502(a)—when shipped, the labeling of the articles contained false and misleading representations that the *electric massage pillows* were an adequate and effective treatment for reducing fatty spots and unsightly bulges, relieving aches due to muscular strain, easing nervous tension, increasing blood circulation, and for trimming the figure; that the *Travel-Mate pillows* were an adequate and effective treatment for stimulating circulation, firming up flesh, reducing unsightly bulges, and trimming the figure; and that the *Vibra-Therm pillows* were an adequate and effective treatment for spot reducing, relieving muscle ache, easing tension, stimulating blood circulation to carry away excess fatty tissues, and slimming and trimming the figure.

**DISPOSITION:** 8-9-58. Consent—claimed by Edson, Inc., and released for relabeling. The *electric massage pillows* and *Vibra-Therm pillows* were relabeled and the vibrating mechanisms of the *Travel-Mate massage pillows* were removed and dismantled in lieu of relabeling such pillows.

**5740. Electric vibrator pillow. (F.D.C. No. 41791. S. No. 25-229 P.)**

**QUANTITY:** 18 devices at Madison, Wis.

**SHIPPED:** 3-28-58, from Chicago, Ill., by P. J. Gould Co.

**LABEL IN PART:** (Ctn.) "Tailorized Tru Fit Electric Vibrator Pillow Helps Massage Away Excess Pounds - Relaxes and Eases Nervous Tension \* \* \* P. J. Gould Co., Chicago, Ill."

**RESULTS OF INVESTIGATION:** The label indicated that the device was a corduroy-covered polyether foam-filled cushion containing an electric motor capable of providing vibration action.

**LIBELED:** 6-4-58, W. Dist. Wis.

**CHARGE:** 502(a)—the label of the article, when shipped, contained false and misleading representations that the device was an adequate and effective treatment for reviving sore and tired muscles, relaxing and easing nervous tension, and massaging away excess pounds.

**DISPOSITION:** 6-27-58. Default—delivered to the Food and Drug Administration.

**INDEX TO NOTICES OF JUDGMENT D.D.N.J. NOS. 5701 TO 5740**

**PRODUCTS**

	N.J. No.		N.J. No.
Adhesive bandages. <i>See</i> Bandages.		Chereshfresh (cherry juice)-----	5732
Ake-Ese tablets-----	5709	Chorionic gonadotropine-----	5719, 5720
Aminophylline tablets-----	5707	Clarimycin-----	5702
Arben capsules-----	5721	Clinical thermometers-----	5728
Arthritis, remedies for. <i>See</i>		Cosmetic (subject to the drug	
Rheumatism, remedies, for.		provisions of the Act)-----	5712
Aspirin tablets-----	5708	Crema ointment-----	5712
Bandages-----	5727	DPS Formula Lipotrate tablets--	5734
Beef, iron, and wine preparation--	5726	Darcopherol tablets-----	5733
Bursitis, remedies for. <i>See</i>		De-em timed capsules-----	5707
Rheumatism, remedies for.		Del-Bardex capsules-----	5722
Castile soap-----	5713	Devices-----	5717, 5728, 5736-5740
		vibrator-----	5738-5740



	N.J. No.		N.J. No.
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with amobarbital, capsules containing	5707	Quinine Sulfate capsules	5707
Diabetes, remedy for	5734	Quinidine Sulfate capsules	5707
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Douche solution	5714	Rejuvenator	5715
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vibrator pillows	5738, 5740	Rheumatism, remedies for	5713, 5732
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Folix-B tablets with iron	5711	tablets	5730
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Gold's Nature Brand tablets	5710	Rheumatism, remedies for.	
Gonadotropine, chorionic	5719, 5720	Skin disorders, remedies for	5702, 5713
Gout, remedies for. <i>See</i> Rheumatism, remedies for.		Slenda-Matic devices	5736
Hemorrhoids, remedy for	5712	Soap, castile	5713
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Lumbago, remedies for. <i>See</i> Rheumatism, remedies for.		Sugar-chek	5735
Medicated cream	5713	Sulfadiazine tablets	5707
Mentho He-Lum ointment	5709	Sulfathiazole tablets	5707
Meprobamate tablets	5703-5705	Sulfobromophthalein sodium injection	5725
powder	5705	Suntan lotions	5712
Methyltestosterone sublingual tablets	5707	Theophenyllin tablets	5707
Neo-Histagen tablets	5707	Thermo-Cyclopad, Niagara, Home Unit	5717
Neuralgia, remedies for. <i>See</i> Rheumatism, remedies for.		Thermometers, clinical	5728
Neuritis, remedies for. <i>See</i> Rheumatism, remedies for.		Thyroid tablets	5707
Niagara Thermo-Cyclopad Home Unit	5717	Timecaps	5707
Nibromiphen tablets	5724	Tranquilizer	5703-5705
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Mentho He-Lum	5709	Ulca-tone	5731
		Ulcers, gastric, remedy for	5731
		Urine sugar test tape. <i>See</i> Sugar-chek.	
		Vegetable oils	<sup>1</sup> 5718
		Vibrator devices	5738-5740
		Vitamin preparations	5701, <sup>2</sup> 5706, 5733

## SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

	N.J. No.		N.J. No.
Allan & Co.:		Bennett, Arthur:	
beef, iron, and wine preparation	5726	Arben capsules	5721
Aloe Creme Laboratories, Inc.:		Charm Cosmetics:	
creme ointment and suntan lotion	5712	royal jelly tablets	5730
		Cooperman, Daniel:	
		vitamin capsules	5701

<sup>1</sup> (5718) Injunction issued.<sup>2</sup> (5706) Seizure contested.

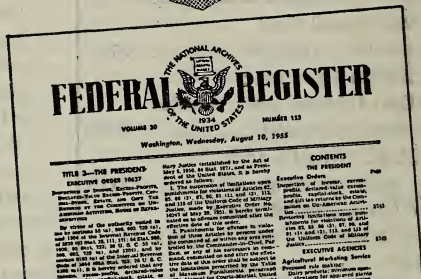
	N.J. No.		N.J. No.
Dartell Laboratories:		Merritt Corp.:	
Darcopherol tablets-----	5733	Clarimycin -----	5702
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tablets -----	5734	royal jelly capsules -----	5729
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vegetable oils-----	<sup>1</sup> 5718	Spartan-Rex Chemical Co.:	
Fulton Thermometer Co.:		Triple-Sulfa No. 1 tablets,	
clinical thermometers-----	5728	Quinidine Sulfate capsules,	
Gould, P. J., Co.:		Quinine Sulfate capsules,	
electric vibrator pillow-----	5740	stilbestrol tablets, sodium	
Grayline Co.:		salicylate tablets, sulfadia-	
Slenda-Matic devices-----	5736	zine tablets, aminophylline	
Groh Co.:		tablets, methyltestosterone	
Nibromiphen tablets-----	5724	sublingual tablets, De-em	
Hall Pharmacal Co., Inc.:		(dextro-amphetamine sul-	
meprobamate tablets-----	5703, 5704	fate) timed capsules, sulfa-	
Hampton Mfg. Co.:		thiazole tablets, thyroid tab-	
adhesive bandages-----	5727	lets, Neo-Histagen tablets,	
Hicks Pharmacal Co.:		Theophenylin tablets, Tim-	
Somnesium capsules-----	5723	caps (dextro-amphetamine	
International Drug Co.:		sulfate capsules), #1 (dex-	
Ake-Ese tablets and Mentho		tro-amphetamine sulfate	
He-Lum ointment-----	5709	with amobarbital) capsules,	
Jones, M. L., Drug Co.:		#2 (dextro-amphetamine	
royal jelly capsules-----	5715	sulfate with amobarbital)	
Kolmar Laboratories, Inc.:		capsules -----	5707
creme ointment and suntan		Strathmore Oils & Fats Co., Inc.:	
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Malaga Oil Products.		Relax-Or cushion-----	5738
Libby, Edwards & Brown, Inc.:		Valabregue, Georges:	
Ulca-tone -----	5731	vegetable oils-----	<sup>1</sup> 5718
Malaga Oil Products Div. of		Van Castle, Charles:	
Leghorn Trading Co., Inc.:		medicated cream, inhalant and	
vegetable oils-----	<sup>1</sup> 5718	rubbing oil, and castile soap-	5713
Medical Chemicals Corp.:		Vitarine Co., Inc.:	
vitamin B <sub>12</sub> injection-----	<sup>2</sup> 5706	sulfobromophthalein sodium	
		injection -----	5725

<sup>1</sup> (5718) Injunction issued.<sup>2</sup> (5706) Seizure contested.

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## U.S. Department of Health, Education, and Welfare

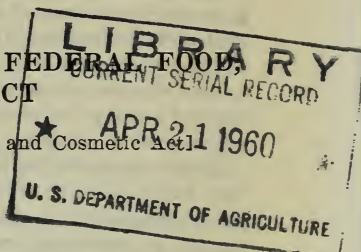
## FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD,  
DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

5741-5780

## DRUGS AND DEVICES



The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were adulterated or misbranded within the meaning of the Act when introduced into and while in interstate commerce or while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings in which decrees of condemnation were entered after default or consent; (2) criminal proceedings terminated by a plea of guilty or nolo contendere or by a judgment of acquittal after trial; and (3) an injunction proceeding terminated by entry of a permanent injunction. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation, and the criminal and injunction proceedings are against the *firms* or *individuals* charged to be responsible for violations.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LABBICK, *Commissioner of Food and Drugs.*

WASHINGTON, D.C., March 24, 1960.

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\*For omission of, or unsatisfactory, ingredient statements, see Nos. 5741, 5745, 5761, 5763; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 5741, 5745; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, No. 5745; cosmetics actionable under the drug provisions of the Act, see Nos. 5750, 5770, 5771.

**SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS  
REPORTED IN D.D.N.J. NOS. 5741-5780**

*Adulteration*, Section 501(b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia), and its strength differed from, and its quality and purity fell below, the standard set forth in such compendium; and Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength differed from, or its purity or quality fell below, that which it purported or was represented to possess.

*Misbranding*, Section 502(a), the labeling of the article was false and misleading; Section 502(b), the article was in package form and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; Section 502(e) (2), the article was a drug not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient including the quantity and kind of alcohol; Section 502(f), the labeling of the article failed to bear (1) adequate directions for use, and (2) adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 502 (1), the article was, or purported to be, or was represented as, a drug composed wholly or partly of tetracycline, a derivative of chlortetracycline, and it was not from a batch with respect to which a certificate or release had been issued pursuant to Section 507; Section 503(b) (1), the article was dispensed without a prescription from a practitioner licensed by law to administer the article; Section 503(b) (4), the article was a drug subject to Section 503(b) (1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

**DRUGS REQUIRING CERTIFICATE OR RELEASE, FOR WHICH NONE  
HAD BEEN ISSUED**

**5741. Achromycin capsules.** (F.D.C. No. 42171. S. No. 4-823 P.)

**QUANTITY:** 2 btl. containing a total of 419 *Achromycin capsules* at Greenbelt, Md., in possession of State Drugs, Inc. (Greenbelt Pharmacy).

**SHIPPED:** The capsules were manufactured in the State of New York, and delivered to the dealer at Greenbelt, Md., by an unknown person, sometime prior to 6-24-58.

**LABEL IN PART:** (Btl.) "Greenbelt Pharmacy \* \* \* 131 Centerway Greenbelt, Md. No. — Dr. — Achromycin 'V'."

**RESULTS OF INVESTIGATION:** The article was in the form of physicians' samples when delivered to the dealer, and after such delivery the article was repackaged into the above-mentioned bottles.

Analysis showed that the article contained approximately 250 milligrams of tetracycline per capsule.

**LIBELED:** 9-4-58, Dist. Md.

**CHARGE:** 502(b) (2)—the label of the article, while held for sale, failed to bear an accurate statement of the quantity of contents; 502(e) (2)—the label of

the article failed to state the active ingredient, tetracycline, by its common or usual name; 502(1)—the article was composed wholly or partly of tetracycline, a derivative of chlortetracycline, and the article was not from a batch with respect to which a certificate or release had been issued pursuant to law; and 503(b) (4)—the article was subject to the provisions of 503(b) (1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 10-31-58. Default—destruction.

**5742. Cosa-Tetracyn capsules, Signemycin capsules, and Tetracyn tablets.**  
(F.D.C. No. 42229. S. Nos. 4-862/4 P.)

QUANTITY: 2 72-capsule btl. of *Cosa-Tetracyn capsules*, 1 18-capsule btl. of *Signemycin capsules*, and 1 23-tablet btl., and 1 8-tablet btl. of *Tetracyn tablets*, at Washington, D.C., in possession of Bretler's Pharmacy.

SHIPPED: Between December 1957 and 9-4-58, from Hillcrest Heights, Md.

RESULTS OF INVESTIGATION: The articles were repackaged by the consignee.

LIBELED: 10-15-58, Dist. Columbia.

CHARGE: 502(1)—the articles contained tetracycline and, while held for sale, were not from a batch with respect to which a certificate or release issued pursuant to law was in effect.

DISPOSITION: 12-3-58. Default—destruction.

**5743. Various drugs.** (F.D.C. No. 42228. S. Nos. 4-855/61 P.)

QUANTITY: 1 195-capsule btl., 1 144-capsule btl., 1 67-capsule btl., and 1 59-capsule btl., of *Cosa-Tetracyn*; 1 94-capsule btl., of *Cosa-Signemycin*; 2 100-capsule btl., of *Cosa-Terramycin*; 1 btl. containing 14 oz. of *Terrabon V*; 8 2-oz. btl., of *Tetra V*; 1 btl. containing 16 oz., and 1 btl. containing 12 oz., of *Signemycin syrup*; and 3 2-oz. btl., and 1 16-oz. btl., of *Terrabon syrup*, at Hillcrest Heights, Md., in possession of Hillcrest Heights Drug, Inc.

SHIPPED: 5-6-58 and 5-14-58, from Alexandria, Va.

RESULTS OF INVESTIGATION: The articles were repackaged by the dealer from physicians' samples after shipment as described above.

LIBELED: 10-14-58, Dist. Md.

CHARGE: All articles, except *Cosa-Terramycin* and *Terrabon syrup*. 502(1)—while held for sale, the articles contained tetracycline and were not from a batch with respect to which a certificate or release was in effect.

*Cosa-Terramycin*. 502(b) (2)—while held for sale, the article failed to bear a label containing an accurate statement of the quantity of contents.

*Terrabon syrup*. 502(b)—while held for sale, the article failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; 502(e) (2)—the label of the article failed to bear the common or usual name of each active ingredient; 502(f) (1)—the label of the article failed to bear adequate directions for use; and 503(b) (4)—the article was a drug subject to 503(b) (1) and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 12-18-58. Default—destruction.



### VIOLATIVE SALES OF PRESCRIPTION DRUGS\*

**5744. Raupentina tablets, Amphocaps capsules, and solution of liver and iron with vitamins.** (F.D.C. No. 40476. S. Nos. 28-655 M, 50-164/5 M, 72-678 M.)

**INFORMATION FILED:** 4-25-58, E. Dist. Pa., against the Professional Products Co., a partnership, and Raymond Steiner, a partner.

**SHIPPED:** Between 11-7-56 and 2-14-57, from Pennsylvania to Connecticut, California, and Illinois.

**LABEL IN PART:** (Btl.) "100 No. 1134 RAUPENTINA (Brand of Rauwolfia Serpentina) 50 Mgm. USUAL DOSAGE: 2 to 3 tablets daily, administered morning and evening. CAUTION: Federal law prohibits sale or dispensing without prescription," "AMPHOCAPS \* \* \* Each capsule contains a total of: Thyroid 3 grs. Amphetamine Sulfate 15 mgm. Phenobarbital  $\frac{1}{4}$  gr.," and "30 cc Multiple Dose Vial LIVER, IRON, with Vitamins B-1 and B-12."

**CHARGE:** *Raupentina tablets.* 502(f) (1)—the labeling of the article failed to bear adequate directions for use for the purposes and conditions for which it was intended; and 503(b) (1)—the article was a drug within the meaning of 503(b) (1) (C) and, while being held for sale by the defendants, was dispensed by the defendants without a prescription from a licensed practitioner.

*Amphocaps capsules.* 503(b) (4)—the article was subject to the provisions of 503(b) (1) and its label failed to bear, prior to its dispensing, the statement "Caution: Federal law prohibits dispensing without prescription."

*Solution of liver and iron with vitamins.* 501(c)—the strength of the article, when shipped, differed from that which it purported or was represented to possess since each 2 cubic centimeters of the article was represented as containing 30 micrograms of vitamin B<sub>12</sub> and 100 milligrams of thiamin hydrochloride, whereas each 2 cubic centimeters of the article contained less than those amounts of vitamin B<sub>12</sub> and thiamin hydrochloride.

**PLEA:** Nolo contendere.

**DISPOSITION:** 11-7-58. The court imposed a fine of \$1,000 against the defendants jointly, and placed them on probation for one year.

### DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS †

**5745. Various drugs.** (F.D.C. No. 42230. S. Nos. 4-841/54 P.)

**QUANTITY:** 2 147-capsule btl. of *glucosamine parenteral tetracycline*; 2 147-capsule btl., and 62 boxes, each containing 2 6-capsule btl., and 30 boxes, each containing 2 10-cc. btl., of *Cosa-Tetracycl*; 1 169-capsule btl., and 20 boxes, each containing 2 4-capsule btl., of *Cosa-Signemycin*; 2 72-capsule btl., and 49 boxes, each containing 2 4-capsule btl., of *Cosa-Terramycin*; 1 6-oz. btl., and 48 boxes, each containing 2 10-cc. btl., of *Signemycin*; 1 14-oz. btl., 1 ctn. of 50 boxes of 2 10-cc. btl. each, 1 ctn. of 48 boxes of 2 10-cc. btl. each, and 1 ctn. of 28 boxes of 2 10-cc. btl. each, of *Tetrabon V*; 1 20-capsule btl. of *Sigmamycin V*; 1 169-capsule btl. of *Cosa-Tetrastatin*; 1 37-capsule btl. of *Tetracycl V*; 1 1,200-capsule btl. of *Terramycin*; 1 49-capsule btl. of *Achromycin V*; 2 75-capsule btl., and 1 150-tablet btl., of *urobiotic capsules Cosa-Terramycin*; and 1 bag containing 12 24-tablet btl.,

\*See also No. 5741.

† See also Nos. 5741, 5744.

and 1 bag containing 15 24-tablet btls., of *Tetracydin*, at Alexandria, Va., in possession of Mount Vernon Service Pharmacy, Inc.

SHIPPED: Between 1-2-58 and 9-4-58, from Brooklyn and Pearl River, N.Y.

RESULTS OF INVESTIGATION: The bottles containing the articles were physician's sample bottles, some of which bore the physician's sample statement, some of which had such statement removed, and some of which were unlabeled.

LIBELED: 10-15-58, E. Dist. Va.

CHARGE: *Cosa-Terramycin capsules*. 502(a)—while held for sale, the label statement "Professional Sample" appearing on the labeled bottles was false and misleading as applied to the article which was not intended for use as physician's samples, but for repackaging and distribution in an uncertified condition and with incomplete labeling; 502(b) (1)—the article, contained in an unlabeled bottle, failed to bear a label containing the name and address of the manufacturer, packer, or distributor; 502(b) (2)—the article, contained in the unlabeled bottle and in the labeled bottles, failed to bear an accurate statement of the quantity of contents.

*Terramycin*. 502(b) (1)—while held for sale, the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; 502(b) (2)—the article failed to bear a label containing an accurate statement of the quantity of contents; 502(e) (2)—the article failed to bear the common or usual name of each active ingredient; 502(f) (1)—the labeling of the article failed to bear adequate directions for use; and 503(b) (4)—the article was a drug subject to 503(b) (1), and its label failed to bear the statement "Caution: Federal Law Prohibits Dispensing Without Prescription."

*Urobiotic capsules Cosa-Terramycin*. 502(b) (2)—while held for sale, the article failed to bear a label containing an accurate statement of the quantity of contents; and 502(e) (2)—the label of the article failed to bear the common or usual name of each active ingredient.

*Cosa-Tetracylin, Cosa-Signemycin, Signemycin, Tetrabon V, and Cosa-Tetracylin*. 502(a)—the label statement "Professional Sample" appearing on the labels of the articles, while held for sale, was false and misleading as applied to the articles which were not intended for use as physician's samples, but for repackaging and distribution in an uncertified condition and with incomplete labeling.

*Glucosamine parenteral tetracycline, Sigmamycin V, Cosa-Signemycin, Cosa-Tetrastatin, Tetracylin V, Achromycin V, Cosa-Tetracylin, Signemycin, Tetracydin and Tetrabon V*. 502(1)—while held for sale, the articles contained tetracycline and were not from a batch with respect to which a certificate or release had been issued.

DISPOSITION: 2-25-59. Default—destruction.

#### DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS\*

5746. Abundavita vitamin tablets, Abundavita mineral tablets, Abundavita protein tablets, and Abundalax tablets. (F.D.C. No. 42151. S. Nos. 16-169/72 P.)

INFORMATION FILED: 8-18-58, E. Dist. Ky., against J. Vincent Reed, D.C., Newport, Ky.

\*See also Nos. 5744, 5745.

**ALLEGED VIOLATIONS:** On or about 2-6-58, the defendant caused an article of drug consisting of 2 bottles of *Abundavita mineral tablets*, 1 bottle of *Abundavita vitamin tablets*, 1 bottle of *Abundavita protein tablets*, and 1 bottle of *Abundalax tablets* to be sold and delivered to an individual at Newport, Ky., without labeling bearing adequate directions in the use of the article for the purposes and conditions for which the article was intended, which act resulted in the article being misbranded while held for sale after shipment in interstate commerce.

**LABEL IN PART:** (Btl.) "Abundavita Food Supplement Vitamin Tablets [or "Mineral Tablets" or "Isolated Vegetable Protein Number One Tablets"]" and "Abundalax A Vegetable Laxative."

**CHARGE:** 502(f) (1)—the labeling of the article failed to bear adequate directions for use for the purposes for which it was intended, namely, for the treatment of cancer, multiple sclerosis, arthritic deformans, cirrhosis of the liver, diabetes, female trouble, and irritation in the pancreas; and for curing all diseases, reducing weight, increasing vitality, and improving health, which were the purposes and conditions for which the article was represented orally by the defendant.

**PLEA:** Not guilty.

**DISPOSITION:** The case came on for trial before the court and jury on 9-24-58. On this same date, after the Government's witnesses had concluded their testimony, the defendant made a motion of acquittal which was sustained by the court.

**5747. Super Protein Formula "90" tablets and Formula "90" Supplement capsules.**  
(F.D.C. No. 41937. S. No. 24-116 P.)

**QUANTITY:** 39 cases of 24 pkgs., each pkg. containing 1 180-tablet btl., and 1 15-capsule btl.; 32 cases of 12 pkgs., each pkg. containing 1 360-tablet btl., and 1 30-capsule btl.; 139 empty 30-capsule size btls.; and 33 empty 360-tablet size btls., at Phoenix, Ariz.

**SHIPPED:** 7-3-57, from Hollywood, Calif., by Hi-Pro Products Co.

**LABEL IN PART:** (Filled btls.) "MpDs \* \* \* Super Protein Formula "90" \* \* \* MpDs is a Balanced Protein Food Supplement"; "Formula "90" Supplement REDUCING \* \* \* to be taken in conjunction with MpDs SUPER PROTEIN TABLETS \* \* \* Each tablet contains: Sodium Carboxy Methyl Cellulose . . . 8 grains Phenylasitin (conc. Prune) . . . 0.5 Mg."; (empty btls.) "Formula "90" Supplement \* \* \* an aid to reducing 30 capsules"; "MpDs \* \* \* Super Protein Formula "90" \* \* \* 360 tablets."

**ACCOMPANYING LABELING:** Pamphlets and placards entitled "Why Be Fat"; and window streamers entitled "MpDs \* \* \* Why Be Fat? Reduce."

**LIBELED:** 7-24-58, Dist. Ariz.

**CHARGE:** 502(a)—the labeling of the articles, when shipped, contained false and misleading representations that the articles contained no calories, would burn up extra fat, increase metabolism, and otherwise act as an adequate and effective treatment for obesity; and 502(f) (2)—the Formula "90" Supplement contained an irritant laxative, and its labeling failed to warn that it should not be used when symptoms of appendicitis are present, and that frequent or continued use of such article may result in dependence on laxatives.

**DISPOSITION:** 9-15-58. Default—destruction.



5748. Brites tablets. (F.D.C. No. 42199. S. No. 4-761 P.)

QUANTITY: 6 display cartons containing a total of 41 bottles at Virginia Beach, Va.

SHIPPED: 7-30-58, from Brooklyn, N.Y., by Commerce Drug Co., Inc.

LABEL IN PART: (Btl.) "25 Tablets BRITES Relieves Hangover \* \* \* Active Ingredients: Salicylamide, Magnesium Hydroxi-amino-acetate, Caffeine, Kola, Mate, Frangula, and Calamus. Directions: \* \* \* Caution: \* \* \* Pektamol Laboratories, Inc., Brooklyn, N.Y. Distributors."

LIBELED: 9-19-58, E. Dist. Va.

CHARGE: 502(a)—the labeling of the article, when shipped, contained false and misleading representations that the article was an adequate and effective treatment for jittery feelings, upset stomach, dizziness, drowsiness, etc., associated with hangover, and would make one feel peppy; and 502(f) (2)—the labeling of the article failed to bear a statement warning that the article should be kept out of reach of children.

DISPOSITION: 10-27-58. Default—destruction.

5749. Rutone capsules and Rutone tablets. (F.D.C. No. 42205. S. No. 35-378 P.)

QUANTITY: 35 boxes at Dallas, Tex.

SHIPPED: From Philadelphia, Pa. This was a return shipment.

LABEL IN PART: (Box) "21 Capsules 42 Tablets \* \* \* RUTONE TWO-WAY PLAN Relieves pain of Arthritis and Rheumatism Distributed by Preston Laboratories, Inc., Chicago, Illinois Each Capsule Contains: Thiamine Mononitrate (Vitamin B-1) 1.0 mg. Ascorbic Acid (Vitamin C) 20.0 mg. P.A.B.A. (Para-Amino-Benzoic Acid) 180 mg. Salicylamide 180 mg. Calcium Succinate 65 mg. Two enteric coated tablets supply: Sodium Salicylate 194 mg. Magnesium Salicylate 129 mg. Calcium Salicylate 129 mg. Each dose consists of two \* \* \* tablets and One Capsule."

ACCOMPANYING LABELING: Leaflet in box entitled "The Rutone Two-Way Plan."

RESULTS OF INVESTIGATION: Analysis showed that the capsules contained less than the declared amount of para-aminobenzoic acid.

LIBELED: 10-8-58, N. Dist. Tex.

CHARGE: 501(c)—the strength of the article, when shipped, differed from that which it purported and was represented to possess, namely, 180 milligrams of para-aminobenzoic acid per capsule; 502(a)—the labeling of the article, when shipped, contained false and misleading representations that the article was an adequate and effective treatment for arthritis, rheumatism, rheumatic fever, osteoarthritis, fibrositis, and gout, and for the pain of such conditions, and that salicylamide, an ingredient of the capsules, was approximately seven times as effective in relieving pain as aspirin; and 502(f) (2)—the label of the article failed to bear a warning to keep it out of the reach of children, and a warning that if pain persisted for more than ten days, or redness was present, a physician should be called immediately.

DISPOSITION: 11-7-58. Default—destruction.

5750. Eileen Cortney multi-formula X21. (F.D.C. No. 41938. S. Nos. 30-494/5 P.)

QUANTITY: 220 8-oz. jars and 288 4-oz. jars at Sayville, N.Y.

SHIPPED: 2-1-58 and 7-11-58, from Chicago, Ill., by Solo Laboratories.

LABEL IN PART: (Jar) "Eileen Cortney Multi-Formula X21 \* \* \* Beauty through the Ages. A balanced topical tissue nutritive compound in a rich base with medicinal quantities of Lecithin, Poly-unsaturates (Vitamin F) and G-11, a prophylatic. Eileen Cortney Inc.—New York Distr. Net Weight 8 oz." "Eileen Cortney Multi-Formula X21 Pentracin Net Weight 4 oz. \* \* \* A topical tissue nutritive with medical values of STABILIZED Polyunsaturates (5%)."

ACCOMPANYING LABELING: Leaflets entitled "For a Healthier Skin" and "Eileen Cortney's Manual of Instructions."

RESULTS OF INVESTIGATION: The leaflets were prepared by Dewey Windale, president of Solo Laboratories, and printed at Sayville, N.Y. The term "G-11" appearing on the label of the 8-oz. jars is the registered trade name of hexachlorophene.

LIBELED: 7-24-58, E. Dist. N.Y.

CHARGE: 502(a)—the labeling of the article, when shipped and while held for sale, contained false and misleading representations that the article was a skin nutritive and an adequate and effective treatment for pre-aged, degenerated skin, psoriasis, all types of flabby, scaly, itching skin, wrinkles, infantile eczema, and atopic dermatitis; 502(e) (2)—the label of the article failed to bear the common or usual name of each active ingredient; and 502(f) (1)—the labeling of the article failed to bear adequate directions for use in that the article was offered as a prophylactic, yet it failed to name the conditions for which its use would produce prophylaxis.

DISPOSITION. 8-26-58. Default—destruction.

## DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

### DRUGS AND DEVICES FOR HUMAN USE\*

5751. D.A.G. antiseptic. (F.D.C. No. 41182. S. Nos. 24-018/9 M.)

INFORMATION FILED: 5-16-58, S. Dist. Calif., against Melchior T. Dikkers, Los Angeles, Calif.

SHIPPED: 1-27-56 and 6-25-56, from California to Arizona.

LABEL IN PART: (Btl.) "Net Contents 4 Ounces or ["One Pint"] D.A.G. Antiseptic \* \* \* Manufactured by Dikkers Biochemical Laboratory, Los Angeles, California.

CHARGE: 501(c)—the strength of the article, when shipped, differed from, and its purity and quality fell below, that which it purported and was represented to possess, in that the article was represented as an antiseptic, whereas it was not an antiseptic but was contaminated with viable organisms. 502(a)—the statements in the labeling of the article, namely, "Antiseptic \* \* \* for minor irritations, cuts, bruises, burns." were false and misleading since the article was not antiseptic, was contaminated with viable organisms, and was not adequate and effective in the treatment of minor irritations, cuts, bruises, and burns. The accompanying labeling of the article, namely, leaflets entitled "D.A.G. Dikkers Antiseptic and Germicide." and "D.A.G. a Theratropic Seaweed Extract with Tri-Iodophenols An Ethical Product for the Dental Profession." contained false and misleading representations

\*See also Nos. 5744, 5749.

that the article was adequate and effective in the treatment of periodontal disease, Vincent's infection, pyorrhea, oral surgery, trench mouth, throat irritations, burns, skin irritations, boils, cuts, abrasions, scratches, prophylaxis for men, rectal irritations, hemorrhoids, colon therapy, athlete's foot, eye irritations, infections, scalds, dermatitis, x-ray lesions, conjunctivitis, iritis, corneal ulcers, chemical burns, coryza, otitis media, sinusitis, tonsillitis, laryngitis, thrush, pruritis anus, fissures, fistula, colitis, amoeba infections, malignancy, gonorrhea, venereal prophylaxis, prostate inflammation, cystitis, hydrocele, leucorrhea, Trichomonas, endometritis, cervicitis, influenza, intestinal and focal toxemia, arthritis, gastric ulcer, duodenal ulcer, thyroid deficiency, cystic goiter, erysipelas, gangrene, carbuncles, furunculosis, abscesses, ulcerations, abrasions, bedsores, and incisions.

PLEA: Guilty.

DISPOSITION: 10-27-58. The defendant was fined \$300 and sentenced to jail for 1 year. The court suspended 11 months of the jail sentence and placed the defendant on probation for 5 years on condition that he serve 30 days in jail.

5752. *Digitalis powder, digitalis tablets, and digitalis capsules.* (F.D.C. No. 42207. S. Nos. 8-567/9 P.)

QUANTITY: 3 10-lb. tins of *digitalis powder*, 64,000 *digitalis tablets* in bottles, and 17,300 *digitalis capsules* in bottles, at Pittsburgh, Pa.

SHIPPED: The *digitalis powder* was shipped on 11-18-58, from New York, N.Y., after having been imported from England.

RESULTS OF INVESTIGATION: The *digitalis tablets* and *digitalis capsules* were manufactured at Pittsburgh, Pa., from *digitalis powder* which had been shipped in bulk as described above.

LIBELED: 9-24-58, W. Dist. Pa.

CHARGE: 501(b)—the strength of the *digitalis powder, tablets, and capsules*, while held for sale, differed from the standards for such drugs set forth in the United States Pharmacopeia; 502(a)—the following label statements: (powdered *digitalis*) "10 International Units of activity in 1.0 gramme" (The U.S.P. *Digitalis Unit* was set by the U.S.P. to conform as closely as possible to the International Unit.), (tablets) "60 mg. (1 Gr.)" and (capsules) "1½ gr. (0.1 Gm.)" were false and misleading as applied to the articles which contained substantially less than their declared potency, namely, (powdered *digitalis*) 10 International Units per gram, (tablets) 1 grain per tablet, and (capsules) 1½ grains per capsule.

DISPOSITION: 10-14-58. Default—destruction.

5753. *Digitalis tablets.* (F.D.C. No. 42170. S. No. 35-125 P.)

QUANTITY: 3 2,000-tablet btls. at Woodbury, N.J.

SHIPPED: 7-22-58, from Philadelphia, Pa., by Raymer Pharmacal Co.

LABEL IN PART: (Btl.) "2000 Tablets Allen's English *Digitalis* 1½ Grains  
\* \* \* Standardized to U.S.P. Requirements for Powdered *Digitalis*."

RESULTS OF INVESTIGATION: Examination showed that the *digitalis potency* of the article was significantly less than its professed potency of 1½ grains of United States Pharmacopeia *digitalis* per tablet.

LIBELED: 9-4-58, Dist. N.J.



CHARGE: 501(b)—the strength and quality of the article, when shipped, differed from the standard for *digitalis tablets* set forth in the United States Pharmacopeia; and 502(a)—the label statement "Digitalis 1½ grains" was false and misleading.

DISPOSITION: 10-9-58. Default—destruction.

**5754. Digitalis tablets.** (F.D.C. No. 42045. S. No. 8-972 P.)

QUANTITY: 1 drum containing 50,000 tablets at Rochester, N.Y.

SHIPPED: Prior to 3-25-58, a quantity of powdered digitalis leaves was shipped from Jersey City, N.J., to Syracuse, N.Y., where it was manufactured into tablets by Mutual Pharmacals Div. of Domfield Co., Inc. On 3-25-58, the tablets were shipped to Rochester, N.Y.

LIBELED: 7-18-58, W. Dist. N.Y.

CHARGE: 501(b)—the strength and quality of the article, while held for sale, differed from the standard for *digitalis tablets* set forth in the United States Pharmacopeia; and 502(a)—the label statement "Each Tablet Contains: Digitalis 1-½ GR." was false and misleading as applied to the article which contained less than 1½ grains of digitalis per tablet.

DISPOSITION: 9-25-58. Default—destruction.

**5755. Ergonovine maleate tablets.** (F.D.C. No. 41885. S. No. 15-402 P.)

QUANTITY: 1 4,800-tablet btl. at Toledo, Ohio.

SHIPPED: 2-14-58, from New York, N.Y.

LIBELED: 6-25-58, N. Dist. Ohio; amended libel, 9-2-58.

CHARGE: 501(b)—the quality and purity of the article, when shipped, fell below the standard for *ergonovine maleate tablets* set forth in the United States Pharmacopeia since the tablets failed to comply with the tests laid down in the Pharmacopeia for absence of "Foreign alkaloids and ergotamine."

DISPOSITION: 10-31-58. Default—destruction.

**5756. Liver-folic acid B<sub>12</sub>.** (F.D.C. No. 42090. S. No. 16-715 P.)

QUANTITY: 149 cartoned vials at Knoxville, Tenn.

SHIPPED: 7-10-57, from Chicago, Ill.

LABEL IN PART: (Vial) "10 cc — Liver-Folic Acid-B<sub>12</sub>. Each cc Contains Vitamin B-12 Activity (From Liver Injection U.S.P. BEEF) Equivalent To: Cyanocobalamin 5 Mcgm. Fortified With Folic Acid 5 Mg. Vit. B-12 Cryst. 25 Mcgm."

RESULTS OF INVESTIGATION: Examination showed that the article contained not more than 34 percent of the declared amount of vitamin B<sub>12</sub>.

LIBELED: 8-15-58, E. Dist. Tenn.

CHARGE: 501(c)—the strength of the article, while held for sale, differed from that which it purported and was represented to possess, namely, an activity equivalent to 30 micrograms of vitamin B<sub>12</sub> per cubic centimeter; and 502(a)—the label statement "Each cc Contains—Vitamin B-12 Activity (From Liver Injection U.S.P. BEEF) Equivalent to: Cyanocobalamin 5 Mcgm. Fortified With Folic Acid 5 Mg. Vit. B-12 Cryst. 25 Mcgm." was false and misleading as applied to the article which contained less than the declared amount of vitamin B<sub>12</sub>.

DISPOSITION: 9-19-58. Default—destruction.

**5757. Dianezenes tablets.** (F.D.C. No. 41556. S. No. 3-548 P.)

QUANTITY: 2 drums containing a total of 21,000 tablets in bulk, and 6 btl., each containing 50 tablets which had been repackaged from bulk stock at Washington, D.C., in possession of the Distribution Center, Inc.

SHIPPED: 6-28-57, from Rensselaer, N.Y., by Delmar Pharmacal Corp.

LABEL IN PART: (Drum) "Lot No. 2531 \* \* \* Special Anti-Radiation Compound (Dianezenes) Each tablet contains: 6½ mg. Vitamin B<sub>1</sub> 100 mg. Nicotinic Acid 100 mg. Ascorbic Acid 6½ gr. Dicalcium Phosphate 200 mg. Iron Reduced N.F. 3½ mg. Pantothenic Acid \* \* \* This is a bulk shipment \* \* \* Delmar Pharmacal, Inc., Rensselaer, N.Y."; (btl.) "Dianezenes \* \* \* Manufactured for the Distribution Center, Inc., Box 242 Silver Spring, Maryland \* \* \* Each Tablet Contains: Nicotinic Acid 100 mg. Vitamin B<sub>1</sub> 6½ mg. Di-Calcium Phosphate 6½ gr. Pantothenic Acid 3½ mg. Ascorbic Acid 100 mg. Iron 333 mg."

RESULTS OF INVESTIGATION: Examination showed that the article contained 198 milligrams of elemental iron, 4.44 milligrams of vitamin B<sub>1</sub>, and 75.5 milligrams of ascorbic acid per tablet.

The article was understood to have been recommended by the consignee for use in preventing and treating harmful effects caused by exposure to radioactivity.

LIBELED: 5-7-58, Dist. Columbia.

CHARGE: 501(c)—the strength of the article, when shipped and while held for sale, differed from that which it purported and was represented to possess since the article contained less than the declared amounts of vitamin B<sub>1</sub>, ascorbic acid, and iron; and 502(a)—the statement on the bulk drum label "Special Anti-Radiation Compound" was false and misleading since it represented and suggested that the article was effective for preventing and treating harmful effects caused by exposure to radioactivity, whereas the article was not effective for such purposes, and the statements on the labels of the article with respect to its content of vitamin B<sub>1</sub>, ascorbic acid, and iron were false and misleading since the article contained less than the declared amounts of such ingredients.

DISPOSITION: 10-1-58. Default—destruction.

**5758. Chorionic gonadotropin.** (F.D.C. No. 42000. S. Nos. 19-949/50 P.)

QUANTITY: 182 packages, each containing 1 2,500-unit vial of *chorionic gonadotropin*, and 1 vial of diluent, and 53 packages, each containing 1 10,000-unit vial of *chorionic gonadotropin*, and 1 vial of diluent at Lincoln, Nebr.

SHIPPED: 4-17-58, from Los Angeles, Calif., by Coast Chemical Co.

LABEL IN PART: (Vial) "Nordens 10 cc Chorionic Gonadotropin 2,500 [or "10,000"] I.U.," and "Nordens 10 cc Chorionic Gonadotropin diluent."

LIBELED: 8-28-58, Dist. Nebr.

CHARGE: 501(c)—the strength of the article differed from that which it was represented to possess, namely, 2,500 I.U. of *chorionic gonadotropin* activity and 10,000 I.U. of *chorionic gonadotropin* activity, respectively; and 502(a)—the label statements "Chorionic Gonadotropin \* \* \* 2,500 I.U." and "Chorionic Gonadotropin \* \* \* 10,000 I.U." were false and misleading as applied to the article the potency of which was substantially less than (182 packages) 2,500 I.U. and (53 packages) 10,000 I.U. of *chorionic gonadotropin* activity.

DISPOSITION: 10-10-58. Default—destruction.

**5759. Rubber prophylactics.** (F.D.C. No. 42131. S. Nos. 26-770 P, 26-773 P.)

**QUANTITY:** 26 cartons, each containing 48 3-unit metal boxes, and 14 cases, each containing 12 cartons of 12-unit boxes each, at Minneapolis, Minn.

**SHIPPED:** 1-16-58, from Akron, Ohio, by Goodwear Rubber Co., Inc.

**LABEL IN PART:** (Box) "Aristocrat \* \* \* for Prevention of Disease" and "Premier Prophylactics."

**RESULTS OF INVESTIGATION:** Examination showed that the article contained holes, and was excessively fragile.

**LIBELED:** 10-6-58, Dist. Minn.

**CHARGE:** 501(c)—the quality of the article fell below that which it purported to possess; and 502(a)—the label statements "Prevention of Disease" and "Prophylactics" were false and misleading.

**DISPOSITION:** 11-20-58. Default—destruction.

**DRUGS FOR VETERINARY USE****5760. Cor-Rex.** (F.D.C. No. 42063. S. No. 24-937 P.)

**QUANTITY:** 53 jugs at Buffalo, Minn.

**SHIPPED:** During 1953 or 1954, from Swea City, Iowa, by Mr. Mortonson.

**LABEL IN PART:** "Master Cor-Rex An Aid In The Control Of Fowl Cholera \* \* \* Active Ingredients 100 cc Contains 23 Grains Mercuric Chloride \* \* \* Directions For Sick Birds \* \* \* Tonic."

**RESULTS OF INVESTIGATION:** Examination showed that the article contained 14.5 grains of mercuric chloride per 100 cubic centimeters.

**LIBELED:** 7-23-58, Dist. Minn.

**CHARGE:** 501(c)—the strength of the article, when shipped, differed from that which it purported or was represented to possess; and 502(a)—the label on the bottle of the article contained false and misleading representations that the article was a tonic, that 100 cubic centimeters of the article contained 23 grains of mercuric chloride, and that the article was an adequate and effective treatment for fowl cholera or any infectious disease of fowl.

**DISPOSITION:** 10-22-58. Default—destruction.

**5761. Blue Seal Chick Starter.** (F.D.C. No. 42200. S. No. 7-592 P.)

**QUANTITY:** 18 100-lb. bags at Nashua, N.H.

**SHIPPED:** 7-7-58, from Lawrence, Mass., by H. K. Webster Co.

**LABEL IN PART:** (Tag) "BLUE SEAL CHICK STARTER Medicated For prevention of coccidiosis and stimulation of growth feed continuously as the only ration. Active ingredients: Glycarbylamide (4,5-imidazoladicarboxamide) 0.002%, Arsanilic Acid 0.01% \* \* \* Manufactured by H. K. Webster Company \* \* \* 31512."

**RESULTS OF INVESTIGATION:** Examination showed that the article contained approximately 0.021 percent sulfaquinoxaline and a trace of arsanilic acid.

**LIBELED:** 9-22-58, Dist. N.H.

**CHARGE:** 501(c)—the quality of the article, when shipped, fell below that which it purported and was represented to possess since the article contained sulfaquinoxaline in place of glycarbylamide; 502(a)—the label statements "Glycarbylamide \* \* \* 0.002%" was false and misleading as applied to a product which did not contain glycarbylamide; and 502(e) (2)—the label of the



article failed to bear the common or usual name of each active ingredient since the presence of sulfaquinoxaline in the product was not declared.

DISPOSITION: 11-10-58. Default—delivered to a county institution for consumption by animals.

### DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS\*

5762. Mill Rue tonic. (F.D.C. No. 42150. S. Nos. 11-293/6 P.)

INFORMATION FILED: 7-22-58, S. Dist. Ill., against Millpax, Inc., Carlock, Ill., and Roy F. Paxton, secretary-treasurer, and director of the corporation.

SHIPPED: Between 9-25-57 and 2-14-58, from Illinois to Indiana.

LABEL IN PART: (Btl.) "MILL RUE Tonic Hematinic Stomachic Contents 8 Fl. Oz. Manufactured by MILL PAX, Inc. Carlock, Illinois."

ACCOMPANYING LABELING: Leaflet entitled "Why Suffer? Take 'Mill Rue' and Enjoy Life As You Live!"

CHARGE: 502(a)—the labeling of the article, when shipped, contained false and misleading representations that the article was an adequate and effective treatment for cancer, ulcers, kidney troubles, and bladder troubles.

PLEA: Guilty.

DISPOSITION: 10-7-58. Corporation fined \$400, plus costs; and individual fined \$800.

5763. Mintola Essence, herb pectoral, and balsam oil. (F.D.C. No. 42183. S. Nos. 12-407/9 P.)

QUANTITY: 15 4-oz. btls., and 15 gals. in bulk, of *Mintola Essence*, 14 8-oz. btls., and 10 gals. in bulk, of *herb pectoral*, and 10 gals. in bulk, of *balsam oil*, in possession of Three V Medical Co., at Oak Park, Ill.

SHIPPED: During 1957 and 1958, various ingredients of the articles were shipped in interstate commerce to Oak Park, Ill., from St. Louis, Mo., New York, N.Y., and Cincinnati, Ohio.

LABEL IN PART: (Btl.) "Three V.V.V. Brand Herb Pectoral or Lung Balsam"; "Three V.V.V. Brand Balsam Oil"; and "Three V.V.V. Brand Mintola Essence or Green Drops."

RESULTS OF INVESTIGATION: The Three V Medical Co. compounded, packaged, and labeled the above-mentioned articles from various ingredients which had been shipped in interstate commerce as described above.

LIBELED: 9-12-58, N. Dist. Ill.

CHARGE: *Mintola Essence*. 502(a)—the labeling of the article, while held for sale, contained false and misleading representations that the article was an adequate and effective treatment for colic, summer complaints, spasmodic pains in stomach, sore throat, swollen tonsils, colds, toothache, earache, chilblains, boils, and frozen limbs; and 502(e) (2)—the label of the article failed to bear the common or usual name of each active ingredient and the quantity and kind of alcohol present in the article.

*Herb pectoral*. 502(a)—the labeling of the article, while held for sale, contained false and misleading representations that the article was an adequate and effective treatment for croup, coughs, bronchial troubles, whooping cough,

\*See also Nos. 5745, 5747-5749, 5751-5754, 5756-5761.

flu and pneumonia; and 502(e) (2)—the label of the article failed to bear the common or usual name of each active ingredient.

*Balsam oil.* 502(a)—the labeling of the article, while held for sale, contained false and misleading representations that the article was an adequate and effective treatment for earache, neuralgia, skin irritations, open wounds, sprains, eczema, swellings, bruises, and caked and sore nipples in cows; and 502(e) (2)—the label of the article failed to bear the common or usual name of each active ingredient and the quantity and kind of alcohol present in the article.

The libel alleged also that a quantity of vanilla extract was adulterated and misbranded under the provisions of the law applicable to foods as reported in notices of judgment on foods.

DISPOSITION: 10-14-58. Default—destruction.

**5764. Ironsol.** (F.D.C. No. 41949. S. No. 38-236 P.)

QUANTITY: 48 unlabeled 1-gal. btls. and 29 individually cartoned 2-oz. btls. at Memphis, Tenn.

SHIPPED: The article was shipped in 55-gal. wooden bbls. sometime in September 1957, from Morton, Miss., by Morton Services, Inc.

LABEL IN PART: (Btl.) "Ironsol Hematinic-Tonic-Stomachic-Active Ingredients: Soluble Iron (as Ferric Sulphate), Aluminum Sulphate and traces of other minerals \* \* \* Distributed by Morton Services, Inc., Morton, Miss."

ACCOMPANYING LABELING: Leaflets designated "Ironsol \* \* \* Minerals Make The Man Or Woman."

RESULTS OF INVESTIGATION: The article in the bottles was repacked by the consignee from the barrels in which it was shipped as described above. The bottle labels and the leaflets referred to above were supplied by the shipper.

LIBELED: 7-25-58, W. Dist. Tenn.

CHARGE: 502(a)—the labeling of the article, when shipped and while held for sale, contained false and misleading representations that the article was effective in the treatment of impaired health, stomach ulcers, nervousness, "nervous indigestion," heartburn, indigestion, sleeplessness, hepatitis, poison ivy, sores in the mouth, gall bladder trouble, allergies, kidney trouble, impaired appetite, loss of weight, sour stomach, loss of vitality, lost manhood, stomach troubles, tingling of the fingers, impaired circulation, infection, and a condition of impure blood; and for producing a stomachic effect.

DISPOSITION: 8-28-58. Default—destruction.

**5765. Sta-Fit (Food supplement).** (F.D.C. No. 41923. S. No. 2-540 P.)

QUANTITY: 487 8-oz. cans and 126 16-oz. cans at Sarasota, Fla.

SHIPPED: Between 5-15-58 and 6-6-58, from Cedar Rapids, Iowa, by Professional Foods Co.

LABEL IN PART: "New 2-Way STA-FIT \* \* \* for both 1: Weight Control 2: Nutritional Supplement Ingredients: Lactalbumin and Soya Protein, Milk Solids (non-fat), Amino Acid, Casein, Methyl Cellulose, Lecithin, Essential lipids from Wheat, Rice, Bran and Soya Bean Oils, Vitamin B-12, Calcium Cyclamate, natural flavors and vitamins from food sources."

ACCOMPANYING LABELING: Folders entitled "You Mean That STA-FIT Can Really Help All of Us?"

LIBELED: 7-11-58, S. Dist. Fla.

CHARGE: 502(a)—the labeling of the article, when shipped, contained false and misleading representations that the article was adequate and effective for the treatment of obesity and for maintaining weight control.

DISPOSITION: 8-12-58. Consent—claimed by Nutritional Service, Inc., Cedar Rapids, Iowa, and relabeled.

**5766. Eifeler tea.** (F.D.C. No. 41848. S. Nos. 3-550/2 P.)

QUANTITY: 250 ctns. bearing a label in the English language and 83 ctns. bearing a label in the German language at Takoma Park, Md.

SHIPPED: On 1-15-58 and in the latter part of April 1958, from Germany by Frau V. Glaremin.

LABEL IN PART: "Eifeler Tea for Diabetes (for the support of treatment for Diabetes) Frau V. Glaremin Julich/Rhld. Germany Walter Timpke \* \* \* Exclusive distributor for America. Directions for use."

ACCOMPANYING LABELING: Leaflets printed in the German language and in the English language entitled "Health Through Nature."

RESULTS OF INVESTIGATION: Examination showed that the article was a mixture of material having the odor and appearances of plant leaf and stem. According to the dealer the article consisted of the plants "Senecio nemorensis" and "Senecio carabinum." The above-named leaflets were printed in Germany at the direction of Walter Tempke, Takoma Park, Md.

LIBELED: 6-4-58, Dist. Md.

CHARGE: 502(a)—the labeling of the article, when shipped, contained false and misleading representations that the article was an adequate and effective treatment for diabetes.

DISPOSITION: 10-31-58. Default—destruction.

**5767. Dietary products.** (F.D.C. No. 41906. S. Nos. 35-469/71 P.)

QUANTITY: 6 1-oz. btl., and 41 5-oz. btl. of *Dr. Bronner's Organic Mineral Salt*; 9 46-oz. btl., and 5 6-oz. btl. of *Dr. Bronner's Organic Carrot Syrup*; and 21 btl. of *Dr. Bronner's Calcium Food* at Schoeneck, Pa.

SHIPPED: 3-14-58, from Los Angeles, Calif., by Dr. E. H. Bronner & Associates.

LABEL IN PART: "Dr. Bronner's Organic Mineral Salt \* \* \* A health food derived from raw Sea & Land Plants High in ocean minerals, iodine, iron & Potassium \* \* \* Stop Tooth Decay The Edible Way \* \* \* Dr. Bronner & Assoc. \* \* \* Escondido, Cal."; "Dr. Bronner's Organic Carrot Syrup \* \* \* contains 18 times more crude minerals, trace elements, carotene Vitamin 'A' & Natural Carrot Sugar than the raw carrots from which it is solely derived \* \* \* Dr. E. B. Bronner & Assoc. \* \* \* Escondido, Cal."; \* \* \* "Dr. Bronner's Calcium Food made with vegetable & mineral calcium, dulse, rosehips, soya, barley yeast, lemon juice, dried Ocean Kelp, sunflower-seed-meal & Barley Malt \* \* \* Dr. E. H. Bronner & Assoc."

ACCOMPANYING LABELING: Leaflets entitled "Organic Mineral Salt & Bouillon" and "Dr. Bronner's Calcium Phosphorus Vegetable."

LIBELED: 7-2-58, E. Dist. Pa.

CHARGE: 502(a)—the labeling of the articles, when shipped, contained false and misleading representations that the mineral salt was effective in preventing tooth decay; that the carrot sirup was effective in correcting poor eyesight; that the calcium food was adequate and effective for preventing tooth decay,



polio, bone brittleness, and loose dentures, and that the right way to prevent tooth decay is with organic-vegetable and oceanic calcium food.

DISPOSITION: 9-16-58. Default—delivered to the Food and Drug Administration.

**5768. Royal jelly capsules.** (F.D.C. No. 41486. S. No. 40-761 P.)

QUANTITY: 2 250-capsule btl.s. and 1 100-capsule btl. at Seattle, Wash.

SHIPPED: 2-6-58, from Los Angeles, Calif., by Healthcraft Products.

LABEL IN PART: "Capsules Healthcraft \* \* \* Jell-E-Vites Royal Jelly \* \* \* Each capsule contains: Royal Jelly 50 mg. \* \* \* Vitamin B<sub>12</sub> \* \* \* 5 mcg. \* \* \* Vitamin B<sub>1</sub> \* \* \* 5 mg. \* \* \* Vitamin B<sub>6</sub> \* \* \* 1 mg. \* \* \* Calcium Pantothenate 5 mg. \* \* \* Niacinamide 10 mg. \* \* \* Vitamin E \* \* \* 5 I.U."

ACCOMPANYING LABELING: Poster of reprints from newspapers and magazines entitled "Famous Newspapers and Magazines Report Sensational Benefits With Royal Jelly."

LIBELED: 3-25-58, W. Dist. Wash.

CHARGE: 502(a)—the labeling accompanying the article, when shipped, contained false and misleading representations that the article would prolong life, cure cancer, rejuvenate failing or worn out glandular activities in human beings, restore vigor, eliminate a feeling of tiredness, restore youthful sex function in women in the menopause, normalize growth of under-developed children, stimulate the appetite, produce a general state of well-being, improve nervous balance, increase virility and sexual energy, have a tonic effect on the mental processes, and cure the ills of old age.

DISPOSITION: 7-9-58. Default—destruction.

**5769. Drugs for sex rejuvenation.** (Inj. No. 278.)

COMPLAINT FOR INJUNCTION FILED: 2-26-54, S. Dist. Calif., against Wayne A. Parkinson, t/a Glandular Products Co., and also t/a Dybutol Co., Long Beach, Calif.; against Allen H. Parkinson, t/a Tide Mailing Service, Long Beach, Calif.; and against Margaret M. Willis, operating manager of the Tide Mailing Service.

CHARGE: The complaint alleged that the defendants were the interstate promoters and distributors of the following articles: *Adler's Compound* (Standard Strength and Super Strength), consisting of vitamins, minerals, and wheat germ oil in an inert glandular base, *Vita-Glan Male Formula* (Regular Strength and Double Strength), consisting of vitamins in an inert glandular base, and *Bio-Glan Male Formula* (Regular Strength and Double Strength) together with *Bio-Glan Fortified Wheat Germ Oil* consisting of vitamins in an inert glandular base and capsules of wheat germ oil; that the promotion and distribution of such articles was carried out as a mail-order business conducted in the names of the Glandular Products Co., and the Dybutol Co.; that substantially all of the normal business functions of such companies, including the printing, addressing, and mailing of labeling of the articles, the receipt and processing of mail orders for the articles, and the bottling, packaging, labeling, and shipping of the articles, in response to the mail orders, were performed or arranged for by the Tide Mailing Service.

The complaint alleged also that the defendants caused the above-named articles to be introduced into interstate commerce with labeling consisting of the labels on the bottles containing the articles, and of various folders, letters, envelopes, and order forms, including folders, entitled "New Safe Bio-

Glan Male Formula"; "Amazing New Vita-Glan"; and "A Report to Physicians and the Public"; and that the articles were misbranded under 502(a), in that their labeling was false and misleading as follows:

*Adler's Compound* (Standard or Super Strength)—the labeling represented and suggested—

(a) That the article was highly efficacious in overcoming male sexual weakness and impotence, whereas it was not efficacious for such purposes;

(b) That the article, which was distributed in the United States by Glandular Products Co., was manufactured in Germany and was available in the United States in limited supply only, whereas the article was manufactured in Los Angeles, Calif., on order of the defendants and was available here in unlimited supply;

(c) That the article was a new and amazing medical miracle developed by outstanding German pharmaceutical knowledge and ingenuity, whereas said drug was composed of commonly known ingredients and was not a new and amazing medical miracle;

(d) That the tablets comprising *Adler's Compound* (Super Strength), differed in composition and potency from the tablets comprising *Adler's Compound* (Standard Strength), whereas all of the tablets were identical in composition and potency; and

(e) That distribution of the article was licensed by the person whose photograph appeared on various items of the labeling, and who was identified there as Konrad Adler, a German specialist in glandular research, whereas the photograph was in fact that of a professional model who resided in Hollywood, Calif., years ago, when the photograph was taken.

*Bio-Glan Male Formula* (Regular and Double Strength), together with *Bio-Glan Fortified Wheat Germ Oil*—the labeling represented and suggested—

(a) That the article was highly efficacious in overcoming male sexual weakness and impotence, whereas it was not efficacious for such purposes;

(b) That the article was marketed by Glandular Products Co., upon the advice and guidance of a medical director, John Garwood, whereas such company had no medical director and the name "John Garwood" was a fictitious one adopted by Wayne A. Parkinson, who was not trained in the field of medicine;

(c) That the tablets comprising *Bio-Glan Male Formula* (Double Strength), had twice the potency of the tablets comprising *Bio-Glan Male Formula* (Regular Strength), whereas all of the tablets were identical in composition and potency; and

(d) That the use of the *Bio-Glan Male Formula* (Double Strength), would create such a rapid sexual rejuvenation in males previously lacking in sexual power as to warrant the use of a double-strength anaesthetic ointment to retard the male sexual climax, whereas the use of such drug would not cause any sexual rejuvenation.

*Vita-Glan Male Formula* (Regular and Double Strength)—the labeling represented and suggested—

(a) That the article was highly efficacious in overcoming male sexual weakness and impotence, whereas it was not efficacious for such purposes;

(b) That the article was highly efficacious in overcoming nervousness, loss of muscle tone, vague aches and pains, fatigue, irritability, headaches, dizziness, weakness, mental depression, insomnia, digestive upsets, loss of appetite, neuritis, backache, and mental dullness, whereas it was not efficacious for such purposes;



(c) That the article was marketed by Glandular Products Co., upon the advice and guidance of a medical director, whereas such company had no medical director;

(d) That the tablets comprising *Vita-Glan Male Formula* (Double Strength), had twice the potency of the tablets comprising *Vita-Glan Male Formula* (Regular Strength), whereas all of the tablets were identical in composition and potency; and

(e) That the use of the *Vita-Glan Male Formula* (Double Strength), would create such a rapid sexual rejuvenation in males previously lacking in sexual power as to warrant the use of an anaesthetic ointment to retard the male sexual climax, whereas the use of such drug would not cause any sexual rejuvenation.

The complaint alleged further that if the defendants were forced by an injunction to discontinue their false and misleading labeling, they would, unless further enjoined, continue their promotion and distribution of the above-named articles and similar articles by making claims for sexual rejuvenation through collateral media outside of labeling, and that, in such case, the articles would be misbranded within the meaning of 502(f)(1), in that their labeling would fail to bear adequate directions for use.

The complaint prayed for the entry of a temporary restraining order and a preliminary and permanent injunction, and also for an order directing the defendants to tender to all present and past purchasers of the above-named articles a refund of all amounts collected by the defendants from such purchasers.

DISPOSITION: On 2-26-54, without notice, a temporary restraining order was entered against the defendants; and on 3-11-54, after a hearing, a preliminary injunction was entered against the defendants enjoining them against the acts complained of.

On 11-5-54, the defendants having consented, a decree of permanent injunction was entered against the defendants enjoining them against introducing into interstate commerce any of the above-named articles, similar articles, or other articles offered for similar purposes, that were misbranded as alleged in the complaint. The decree also provided that the question of restitution was specifically reserved and should be subject to subsequent determination by the court.

Following the entry of the decree, briefs on the question of restitution were submitted by counsel, and, on 7-25-55, argument was held before the court on such question. On 10-21-55, the court handed down the following opinion (135 F. Supp. 208):

CARTER, *District Judge*: "This case poses the question as to whether the district court has power to order restitution in an injunction proceeding under the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. 331-392; Act of June 25, 1938, Chap. 675, 52 Stat. 1040].

"The case is one of first impression under the Food and Drug Laws, although the problem has been discussed recently in law reviews and journals.<sup>1</sup>

<sup>1</sup> Rhyne, *Penalty Through Publicity: FDA's Restitution Gambit*, 7 Food, Drug, Cosmetic L.J. 666-680 (1952)

Noland, *Section 302(a) of the Federal Food, Drug, and Cosmetic Act: Restitution Re-examined*, 7 Food, Drug, Cosmetic L.J. 373-400 (1952)

Lev. *The Nutrilite Consent Decree*, 7 Food, Drug, Cosmetic L.J. 56, 65-67 (1952)

*Developments in the Law—The Federal Food, Drug, and Cosmetic Act*, 67 Harv. LR 632, 718-720 (1954)

Levine, *Restitution—A New Enforcement Sanction*, 6 Food, Drug, Cosmetic L.J. 503-514 (1951)

Goodrich, *Modern Application of an Ancient Remedy*, 9 Food, Drug, Cosmetic L.J. 565-572 (1954)

"*Restitution in Food and Drug Enforcement*," note in 4 Stan. L. Rev. 519-536 (1952).



"The matter was heretofore heard on an application for a preliminary injunction, and a decree of preliminary injunction was made and entered March 11, 1954. Thereafter a final consent judgment, as to permanent injunction only, was made and entered on November 5, 1954.

"The complaint, in addition to praying for general injunctive relief, prayed 'that the defendants be ordered to tender to all present and past purchasers of the drugs enumerated . . . a refund of all amounts collected by said defendants from said purchasers.' By stipulation of the parties, the question is presented as to whether the district court had discretionary power, ancillary to its jurisdiction to grant injunctive relief under 21 U.S.C.A. 332(a), to compel the defendants to refund to purchasers the money paid for the drugs involved in the action, and whether the court has jurisdiction to issue such an order. The question as to whether the court should *exercise* this power, if it possesses it, is reserved by the stipulation for further hearing if necessary. 21 U.S.C.A. Sec. 332(a) reads:

Injunction proceedings—Jurisdiction of courts (a) The district courts of the United States and the United States courts of the Territories shall have jurisdiction, for cause shown, and subject to the provisions of Sec. 381 (relating to notice to opposite party) of Title 28, as amended, to restrain violations of section 331 of this title, except paragraphs (e), (f), and (h)–(j). [Act of June 25, 1938, chap. 675, Sec. 302, 52 Stat. 1054]

We are not concerned with the exceptions.

"We start with the axiomatic premise that the district court is one of limited jurisdiction, and has only the power and the jurisdiction spelled out in the statutory enactments of Congress. We exclude from consideration the general equity power of the court called into play in a diversity suit, and also exclude those situations in which, by statute, the Congress has expressly provided that the court may exercise all the powers of a court of equity. We also exclude from consideration the power of a district court to *compel compliance with its orders when violated or threatened to be violated*. (*McComb v. Jacksonville Paper Co.* (1949) 336 U.S. 187, 193) Sec. 332(b), 21 U.S.C.A., expressly makes reference to a violation of the injunction, and proceedings thereon.

"The plaintiffs predicate their argument on analogy to (a) the Rent and Price Control cases, (b) Fair Labor Standard cases, and (c) the Antitrust cases.

# 1.

## The Rent Control cases.

"In *Porter v. Warner Holding Co.* [1946] 328 U.S. 395, the trial court and the court of appeals both held there was no jurisdiction under the statute to order restitution. The Supreme Court reversed. The statute involved was Sec. 205(a) of the Emergency Price Control Act of 1942, 50 U.S.C.A. App. Sec. 925(a) [56 Stat. 23, 33]. It provided that the administrator might apply to the appropriate court . . . 'for an order enjoining such acts or practices, or for an order enforcing compliance with such provision, and upon a showing by the Administrator that such person has engaged or is about to engage in any such acts or practices a permanent or temporary injunction, restraining order, or other order shall be granted without bond.' [Emphasis added.]

"Sec. 205(a) of the Emergency Price Control Act of 1942 [50 U.S.C.A. App. Sec. 925(a)] first reached the Supreme Court in *Hecht Co. v. Bowles* [1944] 321 U.S. 321. The Supreme Court held that the court could, under the statutory language involved, fashion an appropriate decree to obtain compliance, and at page 328, said:

It seems apparent on the face of § 205(a) that there is some room for the exercise of discretion on the part of the court . . . Though the Administrator asks for an injunction, some "other order" might be more appropriate . . . Such an order, moreover, would seem to be a type of "other order" which a faithful reading of § 205(a) would permit a court to issue in a compliance proceeding.

"In the *Warner Holding* case (*supra*) the Supreme Court, in reversing, rested jurisdiction to issue a mandatory restitution order on two theories. (1) 'as an equitable adjunct to an injunction decree' and (2) 'as an order appro-

priate and necessary to enforce compliance with the Act.' (p. 399-400). It said at page 399:

As recognized in *Hecht v. Bowles* . . . the term "other order" contemplates a remedy other than that of injunction or restraining order, a remedy entered in the exercise of the District Court's equitable discretion.

"Both the *Hecht Co. case*, (supra) and the *Warner Holding Co. case*, (supra) considered legislative history of the statute and Sen. Rep. 931, 77th Cong. 2d Session.<sup>2</sup>

"A portion of the report, quoted in the *Warner Holding Co. case*, (supra) read, "Such courts are given jurisdiction to issue whatever order to enforce compliance is proper in the circumstances of each particular case." (p. 401).

"Subsequently, the Supreme Court in *U.S. v. Moore* [1951] 340 U.S. 616, referring to its decision in *Porter v. Warner Holding Co.* (supra), stated, page 619-620:

This Court reversed, concluding that an order of restitution was a proper "other order." This interpretation was required to give effect to the congressional purpose to authorize whatever order within the inherent equitable power of the District Court may be considered appropriate and necessary to enforce compliance with the Act. . .

Adhering to the broad ground of interpretation of the "other orders" provision adopted in the *Warner case*, we think the order for restitution entered by the District Court in this section was permissible under Section 206(b).<sup>3</sup>

"We are constrained to believe that *Porter v. Warner Holding Co.* (supra) is authority upon the second proposition, namely that a district court had power to grant an order appropriate and necessary to enforce compliance with the Act, based upon the particular wording of the statute. The other ground was not necessary for the decision. Although considered as dicta, it bears great weight, nevertheless we do not believe that the holding of the *Warner case* should be so extended.

"Since the statute in the case at bar does not contain the reference to 'an order enforcing compliance' or 'other order' we do not consider the rent cases as decisive of our problem.

## 2.

### The Fair Labor Standards cases.

"The Fair Labor Standards Act [29 U.S.C.A. Sec. 201-219] and the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. Sections 301-392] were enacted on the same day. [June 25, 1938, 52 Stat. 1060 and 1040 respectively]. Both statutes contained provisions for equitable relief that were almost identical.<sup>4</sup>

"Several appellate court cases ruled that restitution of back pay could properly be ordered as an adjunct to an injunction under Section 17 of the Fair Labor Standards Act, [Sec. 217 U.S.C.A. Title 29] which required the rehiring of a discharged employee. *McComb v. Frank Scerbo & Sons*, 177 F. 2d 137, 138-139 (C.A. 2, 1949); *Walling v. O'Grady*, 146 F. 2d 422, 423, (C.A. 2, 1949). Cf. *Walling v. Miller*, 138 F. 2d 629 (C.A. 8, 1943) which held that the district court had power to embody a restitution order in a consent decree.

"The Supreme Court, however, never ruled on the question expressly, leaving it open in *McComb v. Jacksonville Paper Co.* [1949] 336 U.S. 187-193.

"But Congress, concerned with the appellate courts' interpretations of Sec. 17 of the Fair Labor Standards Act [Sec. 217, U.S.C.A. Title 29] amended the section to provide in express terms that restitution was not

<sup>2</sup> The *Hecht* case cited page 25, the *Warner-Holding* case page 10 of the report.

<sup>3</sup> *U.S. v. Moore*, involves section 206(b) of the Housing and Rent Act of 1947 as amended. This section contains the same "other order" language found in Sec. 205(a) of the Emergency Price Control Act of 1942, involved in *Porter v. Warner Holding Co.* (supra).

<sup>4</sup> Section 17 of the Fair Labor Standards Act [52 Stat. 1069]:

"The district courts of the United States and the United States courts of the Territories and possessions shall have jurisdiction, for cause shown, and subject to the provisions of section 20 (relating to notice to opposite party) of the Act entitled 'An act to supplement existing laws against unlawful restraints and monopolies, and for other purposes' approved October 15, 1914, as amended (U.S.C. 1934 edition, title 28, sec. 381) to restrain violations of section 15."



authorized under the section [Act of Oct. 26, 1949, Chap. 736, Sec. 15, 63 Stat. 919] and other statutory provisions were enacted relating to restitution suits.<sup>5</sup>

"This blunt repudiation by Congress of the asserted powers of a district court to order restitution under Fair Labor Standards Act, with its almost identical provisions to that of Sec. 302(a) of the Food and Drug Act [Sec. 332(a) U.S.C.A. Title 21], is significant and convincing insofar as this court is concerned.

### 3.

#### The Antitrust cases.

"The Government also relies for authority on the injunction suits to restrain violations of the Sherman Act, [15 U.S.C.A. Sec. 4] where the courts have sustained the remedy of divestiture; and cites *Schine Chain Theatres Inc. v. United States* [1948] 334 U.S. 110, holding divestiture to be an equitable remedy and comparing it to restitution; and *United States v. Paramount Pictures* [1948] 334 U.S. 131 to the same effect.

"We are not convinced. The Sherman Act in Sec. 4 U.S.C.A. Title 15, [Act of July 2, 1890, Chap. 647, Sec. 4, 26 Stat. 209 as amended] provides, 'The several district courts of the United States are invested with jurisdiction to prevent and restrain violations of sections 1-7 of this title; and it shall be the duty of the several district attorneys of the United States . . . under the direction of the Attorney General, to *institute proceedings in equity to prevent and restrain* such violations.' [Emphasis added.] This language, read as a whole, clearly empowers the district court with all the remedies of equity. The decisions cited above are then easily understood.

"Nor is divestiture as applied by the courts, the equivalent of restitution. Divestiture requires the defendant to sell his offending interest or stock or properties or to divest himself of his holdings. He is deprived of the offending property at a price. He is not required to restore monies to his competitors by such a decree, though they may, in certain instances, have the remedy of a treble damage suit expressly provided by statute.

### CONCLUSION

"There are fundamental differences in purpose between the Rent and Price Control legislation and the Fair Labor Standards Act on the one hand, and the Federal Food, Drug, and Cosmetic Act on the other. They have been well stated by Rhyne, 'Penalty through Publicity; FDA's Restitution Gambit, 7 Food, Drug, Cosmetic L.J. 666-680 [1952].'

The payment of prescribed sums of money is the essence and purpose of the Fair Labor Standards Act, and also of rent and price control laws. Effectuation of the policies of these laws requires the payment of proper sums. But the Federal Food, Drug, and Cosmetic Act is not concerned with payment of money. Its purpose, or as much of it as is relevant here, is to prevent misbranding; that purpose can be accomplished by a restraining order.

"Restitution, apart from its equitable considerations may also be considered punitive. It is a further method of punishing a defendant in that it requires him to pay over monies in his possession to others. There is a line of authorities that 'an injunction is primarily a preventive remedy; it looks to the future rather than to the past. It is not for the purpose of punishing for wrongful acts already committed,' *High Grade Food Products Corp. v. United States* [8 Cir. 1947] 160 F. 2d 816, and cases cited at page 819; *Minneapolis & St. Louis Ry. Co. v. Pacific Gamble Robinson Co.* [8 Cir. 1950] 181 F. 2d 812 at 814; *American Chicle Co. v. Topps Chewing Gum* [2 Cir. 1954] 210 F. 2d 680 at 683.

"We conclude that the remedy of restitution is not within the powers of the district court under the statute. The Food, Drug, and Cosmetic Act has pro-

<sup>5</sup> Sec. 16(c) [21 U.S.C.A. Sec. 216(c)] was amended and Congress thereby created a special statutory pattern designed (1) to permit an independent suit by the Administrator to collect back pay on behalf of employees, and (2) to protect employers from double litigation by declaring that the employee's consent to such suit constituted a waiver of the employee's statutory right to sue in his own behalf.



vided the sanctions of (1) criminal prosecution and punishment of violators, [21 U.S.C.A. Sec. 333], (2) seizure of goods shipped in violation of the Act [21 U.S.C.A. Sec. 334(a)], and (3) injunctions against further violations, [21 U.S.C.A. Sec. 332(a)]. There is no indication in Congressional history that supports any other sanction or specifically the power to order restitution under the Food, Drug, and Cosmetic Act. The contrary was true in the Congressional history of the Emergency Price Control Act.

"The Government's arguments that such power in a district court, is necessary to effect the essential objectives of the Act and to protect the public's pocket-book, should be addressed to Congress, not to a district court. The jurisdiction and power of this court stem not from things necessary or desirable, but from Congressional action.

"The defendants will submit an order denying plaintiff relief under its prayer for restitution. Pursuant to the stipulation of the parties there remains nothing further to be done in this case. This order denying such relief concludes the case and should therefore be final and appealable."

In accordance with the above opinion, an order was entered on 11-15-55, denying the prayer for restitution set forth in the complaint.

An appeal was taken to the United States Court of Appeals for the Ninth Circuit, and on 11-21-56, the following opinion was handed down by that court (240 F. (2d) 918):

FEE, *Circuit Judge*: "This cause was brought at the instance of Food and Drug Administration, Department of Health, Education and Welfare, in the name of the United States of America against the individuals named as defendants, praying that these latter be restrained from introducing into interstate commerce certain misbranded drugs and requiring defendants to make restitution to purchasers thereof, present and past. The claimed misbranding related to relief from male sexual weakness and impotence and to rapid sexual rejuvenation. A temporary restraining order was granted by the trial court and later extended. Subsequently, after the grant of preliminary injunction, there was entered a judgment by which defendants were permanently enjoined and restrained from doing acts in violation of § 301(a) of the Federal Food, Drug, and Cosmetic Act<sup>1</sup> with respect to all these drugs enumerated, 'or other similar drugs, or other drugs offered for similar purposes.' This portion of the judgment was entered by consent. There was also submitted to the court by stipulation the question whether restitution could be required. The trial court, pursuant to stipulation, divided this into two questions: (1) whether the court had power under the statute to order restitution; and (2) whether restitution would be ordered in this particular case.

"It is difficult indeed to see how any relief could be granted in this case. The supposition is that there were purchasers because there were allegations in the complaint of sales in interstate commerce. But no purchaser was named as a party to the action. The United States did not sue as a representative of any purchaser. There is a suggestion in the prayer only that relief be granted by way of restitution. The body of the complaint contains no allegations upon which the suggestion could be supported. There was no evidence introduced either as to identity of purchasers or as to the amount of drugs unlawfully sold. No judgment could be entered for such refunds, if found in favor of the purchasers themselves, because none was a party to the proceeding. No judgment could be entered in their behalf in favor of the United States or the agency. But besides such technical matters, it was demonstrated that the District Court had no jurisdiction to give such relief under the statute.

"In a sound and able opinion, Hon. James M. Carter, United States District Judge, analyzed the problem, reviewed the statutes and determined that the particular enactment did not confer jurisdiction upon the United States District Courts to make such an order.<sup>2</sup> With this opinion we agree, and the conclusions thereof we affirm. The jurisdiction of the District Court must be found in the language and implications of the particular statute.

<sup>1</sup> 21 U.S.C.A. § 331(a).

<sup>2</sup> *United States v. Parkinson*, 135 Suppl. 208.

"It is agreed that the history and language of the laws for control of monopolization properly permit the application by the courts of orders requiring divestiture of properties of an existing monopolist in order to prevent the continuance of the evil.<sup>3</sup> But the statute<sup>4</sup> under which such relief was granted was much broader in scope than the legislation under consideration, and further divestiture requires only that defendant sell the offending properties at a price, while in the instant case it is sought to force defendant, who has received a price for property which he sold on a free market, to refund such money to be held for a purchaser who paid it willingly. The courts construed certain language of the Price Control Act<sup>5</sup> to compel mandatory restitution.<sup>6</sup> But this legislation was passed and interpreted in time of a struggle for national existence. These laws are now in abeyance and they constitute a doubtful precedent for the extension of enactments such as this which are intended to represent permanent policy in peaceful times as well. These wartime regulations were tremendously unpopular and were deemed arbitrary and oppressive when they were relegated to limbo.<sup>7</sup> An attempt by the Administrator of the Wage and Hour Division to assert the power of collecting restitution was supported by various courts improvidently.<sup>8</sup> The congress rebuked this attempt and in effect repealed the supporting decisions by amending the basic act expressly to forbid collection of restitution by the agency.<sup>9</sup> Since the Fair Labor Standards Act and the Food, Drug, and Cosmetic Act were passed at the same time,<sup>10</sup> an attempt to extend provisions of the latter statute might be similarly rebuked.<sup>11</sup> This feature would not prevent a like construction if the language intentment and history of enforcement thereof convinced us it were a pleadable position. But a diametrically opposite conclusion is forced upon us by these factors.

"The Congress granted three specific powers by this Act. The first was the power to bring criminal prosecutions for violations.<sup>12</sup> The second permitted seizure of drugs proscribed in interstate commerce.<sup>13</sup> The third empowered the courts to restrain violations.<sup>14</sup> Ordinarily, grant of such specific powers would be indicia of the denial of more extensive authority.

<sup>3</sup> See *Sherman Act of 1890*, § 4, 26 Stat. 209, as amended, as construed by *Schine Chain Theatres, Inc. vs. United States*, 334 U.S. 110, 126-130; *United States vs. Paramount Pictures*, 334 U.S. 131, 170-174.

<sup>4</sup> 15 U.S.C.A. § 4 permits the government "to institute proceedings in equity to prevent and restrain such violations," while the Food, Drug, and Cosmetic Act, § 302, 21 U.S.C.A. § 332, grants to the District Court only "jurisdiction, for cause shown \* \* \* to restrain violations of section 331," § 301 of the Act. [Emphasis added.]

<sup>5</sup> Emergency Price Control Act of 1942, § 205(a), 56 Stat. 23, 33, 50 U.S.C.A. App. § 925(a), empowering the court to grant upon a proper showing "a permanent or temporary injunction, restraining order, or other order," without bond. [Emphasis added.]

<sup>6</sup> See *Porter vs. Warner Holding Co.*, 328 U.S. 395, construing the statutory language "other order" to include the remedy of restitution.

<sup>7</sup> A similar result obtains under a similar Act in *United States vs. Moore*, 340 U.S. 616, construing § 206(b) of the Housing and Rent Act of 1947, as amended, 61 Stat. 199, 50 U.S.C.A. App. § 1896(b). However, this Act, like Price Control, was born of wartime stress. It also provides for local termination upon the expression of such a desire by municipalities by resolution made after hearings. § 204(j)(3), 50 U.S.C.A. App. § 1894(j)(3). A similar choice may be made at the State level. § 204(j)(1), (2), 50 U.S.C.A. App. § 1894(j)(1), (2). The former election has already been made in Dallas, Texas. *United States vs. Moore*, supra.

<sup>8</sup> See, for example, *McComb vs. Frank Scerbo and Sons*, 2 Cir., 177 F. 2d 137; *Walling vs. O'Grady*, 2 Cir., 146 F. 2d 422.

<sup>9</sup> The Fair Labor Standards Act of 1938, § 17, 52 Stat. 1069, 29 U.S.C.A. § 217, was amended by the Act of October 26, 1949, 63 Stat. 919, and now reads in pertinent part: "Provided, that no court shall have jurisdiction, in any action brought by the Secretary of Labor to restrain such violations (of 29 U.S.C.A. § 215, entitled in part 'prohibited acts') to order the payment to employees of unpaid minimum wages or unpaid overtime compensation or an additional equal amount as liquidated damages in such action." At the same time, a specific statutory remedy was created, enabling the Secretary of Labor to recover such amounts in any court of competent jurisdiction on behalf of employees to whom such wages were due. Fair Labor Standards Act of 1938, § 16(c), 29 U.S.C.A. § 216(c), as amended by the Act of October 26, 1949, 63 Stat. 919. The authority so conferred was under the most carefully outlined conditions and limitations, which do not exist if this power be conferred by implication from the language of the Food, Drug, and Cosmetic Act.

<sup>10</sup> The Fair Labor Standards Act of 1938, 52 Stat. 1060, et seq., 29 U.S.C.A. § 201, et seq., and the Federal Food, Drug, and Cosmetic Act, 52 Stat. 1040, et seq., 21 U.S.C.A. § 301, were both passed on June 25, 1938.

<sup>11</sup> Especially since § 17 of the Fair Labor Standards Act, 29 U.S.C.A. § 217, before the 1949 amendment, and § 302(a) of the Food, Drug, and Cosmetic Act, 21 U.S.C.A. § 332(a) are substantially identical.

<sup>12</sup> § 303, 52 Stat. 1043, as amended, 21 U.S.C.A. § 333.

<sup>13</sup> § 304, 52 Stat. 1044, as amended, 21 U.S.C.A. § 334.

<sup>14</sup> § 302(a), 52 Stat. 1043, 21 U.S.C.A. § 332(a).



"On account of the importance of the subject, it is necessary to deal with certain arguments made upon appeal.

"There is insistently urged upon us the beneficent purposes of the agency, the necessity of protection of the public and the evils of exploitation of the unwary by fraudulent claims as to drugs the use of which may be harmful. Of course, these elements were the factors which motivated the enactment of the statute. Those who drafted the law and secured passage thereof were fully cognizant of the evils at which it was aimed. Unquestionably, there was a subsidiary purpose to protect the purses of the public and to prevent the vending of alleged remedies, which at best were useless, to fatten the pockets of the exploiter. The agents of the government bring forcibly to our attention our own opinion<sup>15</sup> where the court rightly recognized the harm of permitting the introduction into commerce of drugs of this type. They further emphasize the persistence of the individual defendants here, notwithstanding criminal convictions, decrees of restraint and seizure of drugs, in finding new drugs to exploit by false advertising in order to reap a golden harvest for a short time.

"But advertisements of nostrums for restoration of 'Lost Manhood' have appeared in the daily newspapers for at least fifty years in the past. The drafters of the bill and those who engineered its adoption were cognizant of the persistence of those who desired to make money by such means.

"The record of the past few decades is replete with examples of the tendency of executive agencies to expand their field of operations. A passion and a zeal to crusade affects their operations. Strong public opinion may temporarily encourage excesses in zeal. The enforcement of certain measures based upon worthy causes may induce violent reactions. Examples may be found in the enforcement of laws for prohibition of intoxicants and for the rationing of goods in war. These are warning signs that zeal for the noblest causes should not be translated into uncontrolled power of suppression of the contraries. The courts are charged with the duty of compelling restraint.

"It is particularly urged upon us that a court of equity has power to fashion remedies to meet situations and to compel compliance with decrees. To a certain extent this is correct in litigation between private individuals. But Chancery has ceased for long ages to issue new writs whereby supposed wrongs could be cured. Such objectives are modernly to be accomplished only by legislation. Hundreds of years ago, likewise, equity ceased to be the measure of the 'king's foot.' In litigation between private individuals, the course and remedies of equity became standardized, as these had at common law. The growth of precedent delayed improvident and ad lib expansion.

"Equity had, however, developed a great many devices for enforcement of its decrees. But it was with great reluctance that a mandatory decree was entered even in private litigation. Payment of money held in trust might be required. At times, incidental damages were allowed. Penalties were abominated.

"It was not the fashion of the English Crown to use the Chancery as a method of enforcement of regulations and executive orders. Therefore, the precedents in compulsion to accomplish governmental decretals are found rather in the Court of the Star Chamber, of unhappy memory. The case of the Bishops seems to have forecast an end to this development. In our time, through necessity, cases based upon violations of administrative rules and regulations have been brought in courts which have the traditional equity powers and remedies between individuals.

"When Congress authorizes the enforcement by an administrative body, of rules, regulations or orders promulgated by it, the history of equity and the Court of the Star Chamber in this type of litigation should not be forgotten. The use of the extraordinary remedies of equity in governmental litigation should never be permitted by the courts unless clearly authorized by the statute in express terms. Anything which savors of a penalty should not be permitted unless Congress has expressly so provided, since the spirit of equity abhorred such punitive measures. Here it is apparently contemplated that a judgment be entered in favor of the United States for a definite sum of money for 'restitution.' If the agency were unable or did not give the moneys to the purchasers, it would be covered into the Treasury of the United States.

<sup>15</sup> *United States vs. El-O-Pathic Pharmacy*, 9 Cir., 192 F. 2d 62, 75.



"The collection of moneys not held in trust or earmarked from an individual by an executive department without limitation in amount and without detailed means outlined for disbursement to persons supposed to have paid them constitutes a penalty for violation of a regulation. Indeed, it is with great difficulty, as suggested above, that either the remedy or the word 'restitution' can be twisted or tortured to cover the relief which the agency seeks in this case.

"The holding of the Court is that neither the statute nor any other legislation gives the District Court jurisdiction to grant the relief sought. The equitable powers of the court can not be invoked in the situation because of lack of statutory authority, express or implied.

"We have construed the consent judgment granting injunction and the separate judgment denying so-called 'restitution' as one instrument. The appeal was taken only from the latter part.

"Appeal dismissed."

**5770. Skin cream.** (F.D.C. No. 42061. S. No. 26-445 P.)

**QUANTITY:** 143 cartoned jars at Des Moines, Iowa.

**SHIPPED:** 4-17-58, from New York, N.Y., by Plymouth Cosmetic Corp.

**LABEL IN PART:** (Jar and carton) "Queen Helene Gift of Life Cream with Placental Substance and Skin Nutritives Vital New Medical Cosmetic Formula Containing Youth-Supporting Biogenic Stimulators \* \* \* Para Labs. New York \* \* \* 4 oz."

**ACCOMPANYING LABELING:** Carton insert designated "An Exciting Adventure in Turning Back the Clock" and an advertisement from a Des Moines newspaper prepared from a newspaper mat furnished by the shipper and used as part of a counter display in conjunction with the article.

**LIBELED:** 7-21-58, S. Dist. Iowa.

**CHARGE:** 502(a)—the labeling of the article, when shipped and while held for sale, contained false and misleading representations that the article would act as a skin nutritive; that it would provide biogenic stimulators, youth-producing properties, and the source of life itself; that it would produce a skin that showed no hint of age; and that it would revitalize flabby, loose skin, stimulate circulation, and reinvigorate fibers, bands and cells of the skin.

**DISPOSITION:** 9-10-58. Default—delivered to the Food and Drug Administration.

**5771. DuBarry Creme Natale.** (F.D.C. No. 41939. S. No. 26-554 P.)

**QUANTITY:** 39 cartoned jars at Minneapolis, Minn.

**SHIPPED:** 5-14-58, from Point Lititz, Pa., by Richard Hudnut.

**LABEL IN PART:** (Carton) "DuBarry Creme Natale \* \* \* DuBarry Div. New York Paris Net Wt. 1¾ oz." and (jar) "DuBarry Creme Natale \* \* \* Blended with Placentine, New Scientific Discovery made from the Source of Life Itself."

**ACCOMPANYING LABELING:** Leaflet in carton entitled "Creme Natale Elixir" and display placards designated "New from DuBarry Amazing Preparations."

**LIBELED:** 7-24-58, Dist. Minn.

**CHARGE:** 502(a)—the labeling of the article, when shipped, contained false and misleading representations that the article contained a "Vital Substance" which would provide rebirth of the skin, thus enabling the skin to remain in the "bloom" of babyhood; that the article would provide one with a younger appearance and with a look that was "incredibly younger"; that the article would provide both a softening effect and a tightening effect on the skin; that

the article would overcome the effects of age on the skin, "age signs around eyes and mouth" and wrinkles; and that the article would impart a youthful elasticity to the skin which would banish the drying, faded look of age.

DISPOSITION: 10-22-58. Default—destruction.

**5772. Slenderoll spot reducing device.** (F.D.C. No. 41829. S. No. 26-432 P.)

QUANTITY: 12 devices at Des Moines, Iowa.

SHIPPED: 5-21-58, from Northvale, N.J., by Profile Slenderizing Salons.

LABEL IN PART: "Slenderoll \* \* \* Model No. 161."

ACCOMPANYING LABELING: Warranty slip enclosed with each device.

RESULTS OF INVESTIGATION: The device appeared to be a simple roller massage device containing an electric vibrator.

LIBELED: 6-27-58, S. Dist. Iowa.

CHARGE: 502(a)—the labeling of the device, when shipped, contained false and misleading representations that the device was an adequate and effective treatment for removing excess inches, weight, and fat, stimulating circulation, toning the tissues, and spot reducing.

DISPOSITION: 10-3-58. Default—delivered to the Food and Drug Administration.

**5773. Relaxor vibrator device.** (F.D.C. No. 41888. S. No. 25-847 P.)

QUANTITY: 11 cartons, each containing 12 devices, at New York, N.Y.

SHIPPED: 5-29-58, from Minneapolis, Minn., by Powers Dry Goods Co.

LABEL IN PART: (Label on device) "The Relaxor Vibrator \* \* \* New Vibrating Massager \* \* \* Stantex Mfg. Co."

LIBELED: 7-14-58, S. Dist. N.Y.

CHARGE: 502(a)—the labeling of the article, when shipped, contained false and misleading representations of fact that the article was an adequate and effective treatment for promoting circulation, easing nervous tension, relieving aching back, firming fatty tissues, and reducing thighs, flabbiness and bulges.

DISPOSITION: 8-21-58. Consent—claimed by S. S. Hollender, Inc., New York, N.Y., and relabeled.

**5774. Neurolinometer device.** (F.D.C. No. 40960. S. No. 79-790 M.)

QUANTITY: 6 devices at Cumberland, Wis., in possession of Dr. I. N. Toftness (Toftness Chiropractic Clinic).

SHIPPED: 3-29-56, from Tiffin, Ohio.

LABEL IN PART: "Neurolinometer Toftness System Cumberland, Wisconsin 110 Volts AC Only Serial \* \* \* Power Heater Measure Ten Cervical One Base."

ACCOMPANYING LABELING: Pamphlets designated "The Toftness System of Spinal Correction" and "The Foundation Review" and a book designated "In Sickness . . . and in Health."

RESULTS OF INVESTIGATION: The accompanying labeling of the devices was published at Cumberland, Wis., by Dr. Toftness or by The Foundation for the Advancement of Chiropractic Research, Inc., of which Dr. Toftness was treasurer.

Examination showed that the device consisted of a mono-polar electrode, a single stage amplifier, and a power supply, the output from which was applied to a section of wire mesh attached beneath a sheet of bakelite.

**LIBELED:** 1-2-58, W. Dist. Wis.; amended libel, 4-9-58.

**CHARGE:** 502(a)—the labeling accompanying the article, while held for sale, contained false and misleading representations that the device was capable of measuring nerve interference; of determining accurately the precise line of drive of a subluxation (an incomplete or partial dislocation); of measuring the resistance of a subluxation; of giving the precise line of drive that would most efficiently reduce nerve interference at any given time; of measuring "some types of energy"; of amplifying the impulses which indicate nerve transmission interference; of determining where, when, how much, and how to administer adjustment; and that such diagnostic use of the device could allay, correct, or prevent sickness, disease, death, chronic ailments in children, improper kidney function, and the abnormal function of the stomach and any other organ or part of the body.

**DISPOSITION:** I. N. Toftness, claimant, filed motions for the return of the seized property, the suppression of evidence and dismissal of the action and on 4-9-58, the court denied the motions. Argument was then heard on claimant's objections to answering the written interrogatories which had been served upon him. The court issued an order directing that the claimant answer all of the interrogatories, but that those answers which would "reveal secret processes, development, and information obtained by research all of which was confidential while looking forward to obtaining a patent," could be separated and placed in a sealed envelope subject only to inspection by the court and the Government. The claimant subsequently withdrew his claim, and, on 6-20-58, judgment of condemnation was entered and the devices were ordered delivered to the Food and Drug Administration for display purposes with the provision that they be sold or destroyed after the expiration of one year.

**5775. Filter Queen vacuum cleaner.** (F.D.C. No. 41990. S. No. 20-481 P.)

**QUANTITY:** 28 devices at Kansas City, Mo.

**SHIPPED:** Between 5-1-58 and 7-10-58, from Chicago, Ill., and Cleveland, Ohio, by Health-Mor, Inc.

**LABEL IN PART:** (Top of device) "Filter Queen."

**ACCOMPANYING LABELING:** Folders entitled "Your Doctor Approves Filter Queen Home Sanitation System" and sales manuals entitled "Filter Queen \* \* \* One of the most important developments in home sanitation in 50 years."

**RESULTS OF INVESTIGATION:** The article was a canister-type vacuum cleaner equipped with a cone-shaped cellulose filter intended to remove dirt particles from the inducted air.

**LIBELED:** 8-20-58, W. Dist. Mo.

**CHARGE:** 502(a)—the labeling of the article, when shipped, contained false and misleading representations that the article was capable of preventing streptococcal infection of the sinuses, lungs, brain, spinal cord, blood, joints, middle ear bones, tuberculosis, scarlet fever and diphtheria; preventing such disease conditions as erysipelas, acute abscess and peritonitis, angina, scarlet fever, bronchopneumonia, meningitis, pleurisy, mastoiditis, septic sore throat, arthritis, pulmonary tuberculosis, septic diphtheria, smallpox, measles, an-



thrax, tetanus, whooping cough, enteritis, asthma, and skin and lung cancer; and would protect against such disease-forming bacteria as staphylococci, streptococci, sarcinae, tetrads, hemolytic and non-hemolytic bacteria, and gas formers.

DISPOSITION: 8-21-58. Consent—claimed by Filter Queen of Mid-America, Inc., Kansas City, Mo., and relabeled.

**5776. Healthmore chair.** (F.D.C. No. 41706. S. No. 28-502 P.)

QUANTITY: 13 devices at New Orleans, La.

SHIPPED: 5-1-58, from North Hollywood, Calif., by Wizard Mfg. Co.

LABEL IN PART: "Healthmore Model 500 \* \* \* Custom Built by Wizard Mfg. Co. North Hollywood Calif."

ACCOMPANYING LABELING: Leaflets entitled "Wizard Healthmore Chair."

RESULTS OF INVESTIGATION: The device was indicated to be an upholstered, foam rubber cushioned, reclining, and oscillating chair equipped with a heating element and capable of providing vibration.

LIBELED: 5-15-58, E. Dist. La.

CHARGE: 502(a)—the labeling of the device, when shipped, contained false and misleading representations that the device was effective for overcoming arthritis, bursitis, rheumatism, poor blood circulation, fatigue, tension, and for providing improved health.

DISPOSITION: 9-12-58. Consent—claimed by Wizard Mfg. Co. and relabeled.

**5777. Vibrator device.** (F.D.C. No. 42071. S. No. 26-457 P.)

QUANTITY: 14 devices at Des Moines, Iowa.

SHIPPED: At various times, after 1-1-58, from Milwaukee, Wis., by Hallmark System.

LABEL IN PART: (Metal plate on device) "Hallmark System."

ACCOMPANYING LABELING: Brochures entitled "A New Idea By Hallmark."

RESULTS OF INVESTIGATION: The device was an upholstered, carrying case-type device containing an electric motor providing vibration.

LIBELED: 7-31-58, S. Dist. Iowa.

CHARGE: 502(a)—the labeling accompanying the article, when shipped and while held for sale, contained false and misleading representations that the article was an adequate and effective treatment for arthritis, bursitis, rheumatism, relieving simple constipation, stimulating blood circulation, relieving aches and pains, breaking down fatty tissues, and reducing "anywhere you have excess weight."

DISPOSITION: 9-9-58. Default—delivered to Food and Drug Administration.

**5778. Uranium Wonderpads and Uranium Wondergloves.** (F.D.C. No. 41880. S. No. 9-394 P.)

QUANTITY: 5 *Uranium Wondergloves* and 9 *Uranium Wonderpads* at Buffalo, N.Y.

SHIPPED: 5-26-58, from Jackson, Pa., by Jackson Uranium Corp.

LABEL IN PART: "Uranium Wonderpad [or "Wonderglove"] Jackson Uranium Corp. Susquehanna, Pa."

ACCOMPANYING LABELING: Leaflets entitled "Uranium Wonderglove," and "Uranium Wonderpad"; a form letter entitled "The Jackson Uranium Corpo-

ration is a Diversified Firm"; testimonial letters signed "Mrs. Clara E. Rivenburg" or "Mrs. J. H. Hall" or "Mrs. Doris M. Massingill"; a letter dated June 4, 1955, reading in part "Sal Licata - By our latest telephone conversation"; a handwritten letter dated June 5, 1958, reading in part, "Dear Sal, They are printing at this time—"; and a handwritten note on Jackson Uranium Corp. order blank reading in part "May 29, 1958, Dear Sal, Kindly find enclosed pictorial page."

**RESULTS OF INVESTIGATION:** Examination showed that the Wonderglove was a cloth mitt-type, padded glove with an overall length of 11½ inches, and a width at widest point of 7¾ inches; that the Wonderpad was a cloth pillow, 11 inches by 7¾ inches by ½ inch thick; and that neither of the articles showed any detectable radioactivity when examined by Beta-Gamma Survey Meter Serial BG-3.

**LIBELED:** 6-23-58, W. Dist. N.Y.

**CHARGE:** 502(a)—the labeling of the articles, when shipped, contained false and misleading representations that the articles were an adequate and effective treatment for arthritis, rheumatism, and aches and pains.

**DISPOSITION:** 8-1-58. Default—delivered to the Food and Drug Administration.

#### DRUGS FOR VETERINARY USE

**5779. Vetrodine.** (F.D.C. No. 42152. S. No. 74-189 M.)

**INFORMATION FILED:** 8-1-58, N. Dist. Calif., against Vetrochem, a corporation, Berkeley, Calif., and Jay W. Chilton, president.

**SHIPPED:** 11-13-57, from California to Washington.

**LABEL IN PART:** (Can) "Net Contents 1 Lbs. VETRODINE An iodine medication for livestock only Each ounce contains: Betaine Hydrochloride—25 grains Inert material—q.s."

**ACCOMPANYING LABELING:** Folders designated "Vetro-Thiazine, Flukill, Vetrodine"; and leaflets designated "Suggested Dosages for Use in Manufactured Feed Mixes" and "Vetrodine."

**CHARGE:** 502(a)—the labeling of the article, when shipped, contained false and misleading representations that the article would be effective in the treatment and prevention in livestock of foot rot, abscess, lumpy jaw, necrotic stomatitis, calf diphtheria, respiratory infections and other chronic infections, that the article would aid in the treatment of subacute and chronic mastitis in livestock and of sterility in livestock.

**PLEA:** Guilty.

**DISPOSITION:** 10-9-58. Corporation fined \$100; individual fined \$100, which was suspended, and placed on probation for one year.

**5780. Worm control preparation.** (F.D.C. No. 41907. S. No. 35-342 P.)

**QUANTITY:** 84 1-qt. btls. at Quakertown, Pa.

**SHIPPED:** 4-14-58, from Nashville, Tenn., by Blue Ace.

**LABEL IN PART:** (Btl.) "Blue Ace \* \* \* Poultry-Turkey-Broiler (large round) Worm Control Preparation \* \* \* Active Ingredients—Combined Iodine 3% Nicotine 18% - Inert Ingredients 79% Blue Ace Nashville, Tennessee \* \* \* Sines Hatchery Quakertown, Pa. National Distributors"; and (sticker label) "Simple directions for treating layers, turkeys and growing stock. Dilute 1 teaspoon of Blue Ace in quart of water then sprinkle on top of mash or pellets in hoppers. Treats 100 Birds Daily."

ACCOMPANYING LABELING: Leaflets entitled "Blue Ace."

RESULTS OF INVESTIGATION: The above-mentioned leaflets were printed at Nashville, Tenn., at the request of the shipper and sent directly to the dealer on or about January 29, 1958.

LIBELED: 7-2-58, E. Dist. Pa.

CHARGE: 502(a)—the labeling of the article, when shipped, contained false and misleading representations that the article, when used as directed, was an effective treatment for worms in poultry; that the worming of chickens would increase the hatchability of eggs; and that feeding of the article would increase egg size.

DISPOSITION: 8-6-58. Default—destruction.

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<sup>1</sup> (5746) Prosecution contested.

<sup>2</sup> (5769) Injunction issued. Contains opinions of the courts.



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<sup>1</sup> (5746) Prosecution contested.<sup>2</sup> (5769) Injunction issued. Contains opinions of the courts.

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<sup>1</sup> (5746) Prosecution contested.<sup>2</sup> (5769) Injunction issued. Contains opinions of the courts.

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## U.S. Department of Health, Education, and Welfare

U.S. DEPARTMENT OF AGRICULTURE  
FOOD AND DRUG ADMINISTRATIONNOTICES OF JUDGMENT UNDER THE FEDERAL FOOD,  
DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

5781-5820

## DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involved drugs and devices which were adulterated or misbranded within the meaning of the Act when introduced into and while in interstate commerce or while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings in which decrees of condemnation were entered after default or consent; (2) criminal proceedings terminated upon pleas of guilty; and (3) a contempt proceeding for violation of an injunction which was terminated by a supplemental consent decree. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation; and the criminal and contempt proceedings are against the *firms* or *individuals* charged to be responsible for violations.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D.C.

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SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS  
REPORTED IN D.D.N.J. 5781-5820

*Adulteration*, Section 501(b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia), and its strength differed from, and its quality and purity fell below, the standard set forth in such compendium; Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength differed from, or its purity or quality fell below, that which it purported or was represented to possess; and Section 501(d)(2), the article was a drug, and a substance had been substituted wholly or in part therefor.

*Misbranding*, Section 502(a), the labeling of the article was false and misleading; Section 502(b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; Section 502(d), the article contained a chemical derivative of codeine, and its label failed to bear the name, and quantity of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming"; Section 502(e), the article was a drug not designated solely by a name recognized in an official compendium, and its label failed to bear (1) the common or usual name of the drug; and (2) the drug was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient; Section 502(f), the labeling of the article failed to bear (1) adequate directions for use and (2) adequate warnings against use in those pathological conditions, or by children, where its use may be dangerous to health, or against unsafe dosage or methods of duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 502(g), the article purported to be a drug, the name of which is recognized in an official compendium (United States Pharmacopeia), and it was not packaged as prescribed therein; and Section 502(i)(3), the article was a drug offered for sale under the name of another drug.

**DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR  
ADEQUATE DIRECTIONS OR WARNING STATEMENTS**

**5781. Hoxsey treatment for internal cancer.** (Inj. No. 311.) Supplement to D.D.N.J. No. 5202.

**PETITION FILED:** On 10-6-58, a petition for an order to show cause in criminal contempt was filed in the Western District of Pennsylvania, against Hoxsey Cancer Clinic, a corporation, Portage, Pa., and John J. Haluska, Samuel J. Einhorn, John H. Benko, Harold F. Galbraith, A. A. Nelson, and Harry A. Stegman, incorporators, directors, and trustees of the clinic.

**DISPOSITION:** On 10-30-58, the following supplemental consent decree was entered:

*MILLER, District Judge:* "AND NOW, to wit, this 30th day of October, 1958, the United States of America having filed a petition for order to show cause why the defendants should not be punished for criminal contempt of this Court's permanent injunction, which became effective November 1, 1957, and the Court being convinced that the terms of this supplemental decree and the provisions thereof are necessary to effectuate the operation of this Court's orders and decrees, and the defendants having expressed to the Court a willingness to dissolve the corporation and to wind up its business of delivering medicine to persons at Portage, Pennsylvania, and having consented to this supplemental consent decree;

"It is ORDERED, ADJUDGED AND DECREED that the defendants shall dissolve the said corporation and on or before November 1, 1958 completely discontinue the operation of the Hoxsey Cancer Clinic at Portage, Pennsylvania; that the said defendants, and each of them, shall not after that date reopen the said clinic under the name of the Hoxsey Cancer Clinic or any other name for the treatment of any person or persons for cancer, and shall not assign, lease or sell the said clinic to any other persons or organization except with the approval of this court; that the decree entered October 2, 1957 shall continue in full force and effect; that defendants' failure to comply with this supplemental consent decree may be prosecuted as a criminal contempt, and that upon defendants' failure to comply with this supplemental consent decree the Court will immediately sign the order to show cause that is now pending and shall schedule the case for an early trial.

"The Food and Drug Administration is directed to report to the Court, not later than December 1, 1958, whether the defendants are in full compliance with this decree."

**5782. Zina-Ray Oil, inhalers, and Ten Second Rub.** (F.D.C. No. 42158. S. No. 24-906 P.)

INFORMATION FILED: 10-17-58, Dist. Minn., against William R. Hall, Minneapolis, Minn.; amended information filed, 11-17-58.

ALLEGED VIOLATION: On 1-23-58, at a public sales talk in Minneapolis, Minn., the defendant caused oral representations to be made holding the articles out to the public as a treatment for the diseases, symptoms, and conditions set forth below, which act resulted in the articles being misbranded while held for sale after shipment in interstate commerce.

LABEL IN PART: (Drug) "Zina-Ray Oil \* \* \* Contains Eucalyptus Oil, Menthol, Pine Needle Oil, Peppermint Oil. Contents 3 Fl. Oz."; (device) "25¢ Inhaler 25¢"; (tube) "Ten Second Rub \* \* \* Net Weight 3 fluid oz."

CHARGE: 502(f) (1)—the labeling of the articles failed to bear adequate directions for use in the treatment of the diseases, symptoms, and conditions for which the articles were intended, namely, (*Zina-Ray Oil* and *inhalers*) for preventing headaches, pain in the gums, neuralgia, deafness, arthritis, rheumatism, formation of crystal deposits in the bones, inflammation of the ear, pneumonia, "flu", and overcoming sinus infection and asthma; and (*Ten Second Rub*) for overcoming arthritis, rheumatism, and all aches and pains to which the body is subject.

PLEA: Guilty.

DISPOSITION: 1-26-59. \$500 fine and sentence of 4 months in prison.

**5783. Dasin C. S. capsules.** (F.D.C. No. 41740. S. No. 79-505 M.)

INDICTMENT FILED: 7-31-58, E. Dist. N.Y., against Charles P. Greenberg, and Marvin Goldstein, partners in the partnership of Page Drugs, Bethpage, N.Y.

ALLEGED VIOLATIONS: On 10-19-57, while a number of *Dasin C. S. capsules* were being held for sale by the defendants after shipment in interstate commerce, the defendants caused to be dispensed, delivered, and sold to a customer, a number of such tablets in place of the Panalba capsules called for in the prescription which was presented by the customer to the defendants for filling. Such acts resulted in the *Dasin C. S. capsules* being adulterated and misbranded as described below.

CHARGE: 501(c)—the strength of the article differed from that which it purported and was represented to possess; 501(d) (2)—*Dasin C. S. capsules* had been substituted for Panalba capsules; 502(a)—the statement on the vial label of the article contained false and misleading representations and suggestions



that the article was Panalba capsules; 502(b)(2)—the label of the article bore no statement of the quantity of contents; 502(d)—the article contained a chemical derivative of codeine, namely, codeine sulfate, which derivative had been found to be, and by regulations designated as, habit forming, and the label of the article failed to bear a statement of the quantity of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming"; 502(e)(1)—the label of the article failed to bear the common or usual name of the article, namely, Dasin C. S.; 502(e)(2)—the label of the article failed to bear the common or usual name of each active ingredient in each capsule of the article, including the name, quantity, kind, and proportion of acetophenetidine and atropine or any derivative of any such substances contained therein; 502(f)(1)—the labeling of the article failed to bear adequate directions for use; 502(f)(2)—the labeling of the article failed to bear such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods of administration or application, in such manner and form, as are necessary for the protection of users; and 502(i)(3)—the article was offered for sale under the name of another drug.

PLEA: Guilty.

DISPOSITION: 12-5-58. Each defendant was fined \$1,500, given a jail sentence of 1 year, which was suspended, and placed on probation for 3 years.

**5784. Vitamin-mineral supplement, Special Formula dietary supplement, inhalant & rubbing oil, and salve. (F.D.C. No. 42231. S. Nos. 25-277/80 P.)**

QUANTITY: 318 60-tablet btl. of *vitamin-mineral supplement*, 18 btl. *Special Formula dietary supplement*, 136 1-oz. vials *inhalant & rubbing oil*, and 144 2-oz. tins of *salve*, at Mitchell, S. Dak.

SHIPPED: At various times, from outside the State of South Dakota.

LABEL IN PART: (Btl.) "Napier's 14 & 10 (Improved) Vitamins-Minerals A dietary supplement \* \* \* Prepared for Chief D. A. Napier, R.R. #3—Tahlequah, Okla." and "Napier's Special Formula E.P. A high potency dietary supplement furnishing a wide range of vitamins and minerals \* \* \* Distributed by Chief D. A. Napier"; (tin) "Napier's Family Salve Active Ingredients: Methyl Salicylate, Oil Pine Tar and Balsam Peru in a Petrolatum base \* \* \* Chief D. A. Napier"; (vial) "Napier's Inhalant & Rubbing Oil \* \* \* Active Ingredients: Eucalyptus Oil, Menthol, Peppermint Oil, Thymol, Camphor \* \* \* Chief D. A. Napier."

ACCOMPANYING LABELING: Booklets entitled "Napier's Health Book" and leaflets entitled "Chief Don A. Napier and Family \* \* \* How Vitamins & Minerals Help The Whole Family—The Price of Health."

LIBELED: 10-21-58, Dist. S. Dak.

CHARGE: 502(a)—the labeling accompanying the *vitamin-mineral supplement* and the *Special Formula dietary supplement*, while held for sale, contained false and misleading representations that the articles were effective in the prevention and treatment of tuberculosis, heart disease, liver and kidney disorders, gout, jaundice, skin diseases, indigestion, sexual weakness or impotence, mental deficiency, diabetes, catarrh, sores that do not heal, arthritis, rheumatism, chronic bronchitis, and cirrhosis of the liver; and 502(f)(1)—while held for sale, all the articles failed to bear adequate directions for the uses for which they were intended, namely, (*vitamin-mineral supplement*) for



treatment of arthritis and rheumatism, high blood pressure, improving eyesight, and insuring general good health; (*Special Formula dietary supplement*) as a "make man" remedy to restore lost manhood, improve sexual powers, and for sexual rejuvenation generally; (*inhalant and rubbing oil*) for the treatment of sinus trouble, catarrh, asthma, hay fever, colds, grippe, earache, chest colds, chilblains, pain in the back, neck, or leg; and (*salve*) for all kinds of burns or scalds, eczema, impetigo, skin rashes, poison oak, poison ivy, ringworm, itching, bleeding, blind or protruding hemorrhoids, and varicose vein sores; which were the purposes and conditions for which the articles were offered for sale orally by the distributor, Don A. Napier, in a sales talk at Mitchell, S. Dak.

**DISPOSITION:** 12-2-58. Default—the *vitamin-mineral supplement* and the *Special Formula dietary supplement* were delivered to a public institution for its use, and the other articles were destroyed.

**5785. Integrated therapy capsules and ointment.** (F.D.C. No. 42239. S. Nos. 42-104/5 P.)

**QUANTITY:** 4 pkgs., each containing 1 jar of ointment and 1 30-capsule btl., and 13 90-capsule btls., at Billings, Mont.

**SHIPPED:** 8-14-58, from Paris, Tenn., by Golden Peacock Toiletries.

**LABEL IN PART:** (Pkg.) "Integrated Therapy Capsulate & Ointment \* \* \* Mitchum Distributors Paris, Tennessee"; (jar) "Net Wt. 1 Oz. Integrated Therapy Ointment \* \* \* Contains 1% Ammoniated Mercury, Sorbitol, Hexachlorophene, and Natural Estrogens, Principally Estrone, equivalent to 10,000 I.U. per ounce. Directions \* \* \* 3223"; (btl.) "30 [or "90"] Capsules Integrated Therapy Capsulate \* \* \* Each Capsule Contains Palmitate 12,500 USP Units Irradiated Ergosterol 1,000 USP Units Thiamine Hydrochloride USP 5.0 mg. Riboflavin USP 2.5 mg. Pyridoxine Hydrochloride .5 mg. Vitamin B-12 1.0 mg. Ascorbic Acid USP 75.0 mg. Niacinamide USP 40.0 mg. Calcium Pantothenate 4.0 mg. d-alpha Tocopheryl Acetate . . . equivalent to 2 I.U. Vit. E Folic Acid USP 0.5 mg. Dicalcium Phosphate, Anhydrous 260.0 mg. Calcium 75.0 mg. Phosphorous 58.0 mg. Choline Bitartrate 31.4 mg. Inositol 15.0 mg. di-Methionine 10.0 mg. Ferrous Sulfate \* \* \* (iron 30 mg.) 102.0 mg. Cobalt Sulfate \* \* \* .193 mg. Copper Sulfate \* \* \* 1.257 mg. Manganese Sulfate \* \* \* 1.573 mg. Sodium Molybdate .253 mg. Potassium Iodide USP \* \* \* .099 mg. Zinc Sulfate \* \* \* 1.388 mg. Magnesium Sulfate \* \* \* 21.583 mg."

**ACCOMPANYING LABELING:** Leaflets entitled "Valuable Free Merchandise Certificate," "Happy Days are Here Again Since We Discovered Integrated Therapy Capsulate," and "Instructions for Use."

**LIBELED:** 10-27-58, Dist. Mont.

**CHARGE:** 502(a)—the labeling of the articles, when shipped, contained false and misleading representations that the articles were an adequate and effective treatment for making one feel and look younger, combating signs of age, lack of sleep, loss of mental and physical ambition, aches and pains, needless worry and sexual weakness, and that the articles would produce a new glow of inner health and vitality and would eliminate wrinkles and firm the skin; and 502(f) (2)—the ointment contained a mercury compound, and its labeling failed to warn that users should discontinue the use of the article if irritation of the skin developed, and that frequent or prolonged use or application to large areas may cause serious mercury poisoning.

**DISPOSITION:** 12-1-58. Default—destruction.

## DRUG FOR VETERINARY USE

5786. **Blue Seal Growing Mash.** (F.D.C. No. 42201. S. No. 7-887 P.)

QUANTITY: 132 100-lb. bags at Ellsworth, Maine.

SHIPPED: 7-9-58, from Lawrence, Mass., by H. K. Webster Co.

LABEL IN PART: (Tag) "BLUE SEAL GROWING MASH"; (bag) "BLUE SEAL GRAIN PRODUCTS \* \* \* Manufactured by H. K. Webster Company."

RESULTS OF INVESTIGATION: The article was invoiced as "1 Lb. G.C. per ton."

LIBELED: 10-1-58, Dist. Maine.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it purported and was represented to possess since the article contained sulfaquinoxaline in place of glycarbylamide; 502(e)(2)—the label of the article failed to bear the common or usual name of each active ingredient contained therein since the presence of sulfaquinoxaline was not declared; and 502(f)(1)—the labeling of the article failed to bear adequate directions for use.

DISPOSITION: 11-18-58. Default—destruction.

**DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM  
OFFICIAL OR OWN STANDARDS**

**DRUGS FOR HUMAN USE\***

5787. **Digitalis powder, digitalis tablets, and digitalis capsules.** (F.D.C. No. 42223. S. Nos. 35-138/9 P.)

QUANTITY: 2 5-lb. tins, and 2 3-lb. tins of *digitalis powder*, 17 2,000-tablet btl., 1 1,500-tablet btl., 72 1,000-tablet btl., 1 500-tablet btl., and 1 100-tablet btl. of *digitalis tablets*, and 15 1,000-capsule btl., and 1 500-capsule btl. of *digitalis capsules*, at Philadelphia, Pa.

SHIPPED: The *digitalis powder* was shipped on 11-12-57, from Montreal, Canada, by F. E. Cornell & Co., Ltd.

LABEL IN PART: (Tin) "Allen's Selected Digitalis Leaves in Powder \* \* \* E 62330 This Digitalis Powder contains 14.2 International Units per gramme, or one unit is contained in 0.07 gramme, which is equivalent to 0.076 gramme of the 3rd International Standard Digitalis Powder as determined by a biologic test carried out by the School of Pharmacy, University of London Stafford Allen & Sons, Ltd., London & Louis Medford, England Batch Number 9/M 3/56 2nd November 1956," (btl.) "Tablets [or "Capsules"] Allen's English Digitalis 1½ Grains \* \* \* Standardized to U.S.P. requirements for Powdered Digitalis \* \* \* Raymer Pharmacal Company, Philadelphia, Pa."

RESULTS OF INVESTIGATION: The *digitalis tablets* and *digitalis capsules* were manufactured at Philadelphia, Pa., by the Raymer Pharmacal Co., from *digitalis powder* which had been shipped as described above.

LIBELED: 10-13-58, E. Dist. Pa.

CHARGE: 501(b)—the strength of the articles, when shipped and while held for sale, differed from the standards for *digitalis powder*, *digitalis tablets*, and *digitalis capsules* set forth in the United States Pharmacopeia; and 502(a)—the following label statements: (powder) "This Digitalis Powder contains 14.2 International Units per gramme," and (tablets & capsules) "Digitalis

\*See also Nos. 5783, 5786.

1½ Grains" were false and misleading as applied to the articles since the powder contained significantly less than 14.2 units of digitalis potency, and the tablets and capsules contained significantly less than 1½ grains of digitalis potency per tablet or capsule.

DISPOSITION: 12-22-58. Default—destruction.

**5788. Videxcell tablets, Buta-B tablets (¼ grain), and Buta-B tablets (½ grain).** (F.D.C. No. 41473. S. Nos. 3-492/4 P.)

QUANTITY: 367 100-tablet btl. of Videxcell, 297 100-tablet btl. of *Buta-B tablets* (¼ grain), and 501 100-tablet btl. of *Buta-B tablets* (½ grain), at Arlington, Va.

SHIPPED: Between 1-15-54 and 7-26-55, from Philadelphia, Pa.

LIBELED: 4-11-58, E. Dist. Va.; libel amended, 10-28-58.

CHARGE: *Videxcell tablets*. 501(c)—the strength of the article, while held for sale, differed from that which it was represented to possess, namely, crystalline vitamin A acetate, 1,500 units per tablet; and 502(a)—the label statement "Each Tablet Contains \* \* \* Crystalline Vitamin A Acetate 1,500 Units" was false and misleading as applied to the article which contained less than the declared amount of vitamin A.

*Buta-B tablets* (¼ grain) and *Buta-B tablets* (½ grain). 501(c)—the strength of the articles, while held for sale, differed from that which they were represented to possess, namely, thiamin HCl, 5 milligrams per tablet; and 502(a)—the label statements "Each Table Contains Thiamin HCl \* \* \* 5 mg." were false and misleading as applied to the articles which contained less than the declared amount of vitamin B.

The libel alleged also that two other articles, namely, Conciecaps and Arlvita-Tabs were adulterated and misbranded under the provisions of the law applicable to foods as reported in notices of judgment on foods.

DISPOSITION: 11-4-58. Default—destruction.

**5789. Aspirin tablets.** (F.D.C. No. 41995. S. No. 7-863 P.)

QUANTITY: 5 cases, 144 100-tablet btl. each, at New Haven, Conn.

SHIPPED: In January 1954, from Newark, N.J.

RESULTS OF INVESTIGATION: Analysis showed that the article contained 92 percent of the labeled amount of acetylsalicylic acid, and that it contained a significantly larger amount of free salicylic acid than the maximum of 0.15 percent permitted by the United States Pharmacopeia. The United States Pharmacopeia requires that *aspirin tablets* contain from 95 percent to 105 percent of the labeled amount of acetylsalicylic acid.

LIBELED: 8-23-58, Dist. Conn.

CHARGE: 501(b)—the strength, quality, and purity of the article, while held for sale, fell below the standard for *aspirin tablets* set forth in the United States Pharmacopeia since the article contained less than the required amount of acetylsalicylic acid and more than the permitted amount of free salicylic acid; and Section 502(a)—the label statement "Aspirin Tablets U.S.P. 5 Grains Each" was false and misleading.

DISPOSITION: 1-8-59. Default—destruction.

**5790. Congo red injection.** (F.D.C. No. 42113. S. No. 40-035 P.)

QUANTITY: 6 boxes, 25 10 cc. vials each, and 4 boxes, 6 10 cc. vials each, at San Francisco, Calif.



SHIPPED: Between 1-2-58 and 7-8-58, from Chicago, Ill., by Chicago Pharmacal Co.

RESULTS OF INVESTIGATION: Analysis showed that the article contained pyrogens.

LIBELED: 9-9-58, N. Dist. Calif.

CHARGE: 501(b)—the quality and purity of the article, when shipped, fell below the standard for *Congo red injection* set forth in the United States Pharmacopeia.

DISPOSITION: 11-5-58. Default—destruction.

**5791. Lynnofol and liver injection.** (F.D.C. No. 42293. S. Nos. 35-141/2 P.)

QUANTITY: 47 cartoned vials of *Lynnofol*, and 98 cartoned vials of *liver injection*, at Camden, N.J.

SHIPPED: 6-23-58, from Philadelphia, Pa.

LABEL IN PART: (Vial) "10 cc. Multiple Dose Vial LYNNOFOL (Folic Acid with Liver Liquid)" and "30 cc. Multiple Dose Vial Liver Injection U.S.P. Beef."

RESULTS OF INVESTIGATION: Examination showed that the articles contained not more than 50 percent of the declared amount of vitamin B<sub>12</sub>.

LIBELED: 11-13-58, Dist. N.J.

CHARGE: 501(b)—the strength of the *liver injection*, while held for sale, differed from the official standard for *liver injection* set forth in the United States Pharmacopeia since the potency of the article was less than that stated on its label; 501(c)—the strength of the *Lynnofol*, while held for sale, differed from that which it purported and was represented to possess, namely, vitamin B<sub>12</sub> activity per cubic centimeter equivalent to 20 micrograms cyanocobalamin; and 502(a)—the label statements (*Lynnofol*) "Each cc. contains: \* \* \* Vitamin B<sub>12</sub> activity per cc equivalent to 20 micrograms cyanocobalamin" and (*liver injection*) "Vitamin B<sub>12</sub> activity p. cc equivalent to 10 micrograms cyanocobalamin" were false and misleading as applied to products which contained less than the stated amount of vitamin B<sub>12</sub>.

DISPOSITION: 12-22-58. Default—destruction.

**5792. Clinical thermometers (oral).** (F.D.C. No. 40438. S. No. 23-988 M.)

INFORMATION FILED: 3-18-59, S. Dist. N.Y., against Philbern Thermometer Co., Inc., Bronx, N.Y., and Chester Berns, president.

SHIPPED: 3-30-56, from New York to California.

CHARGE: 501(c)—the thermometers were represented to comply with the requirements of Commercial Standard CS1-52, issued by the National Bureau of Standards of the Department of Commerce, whereas the quality of the thermometers fell below that which they were represented to possess; and 502(a)—the labeling of the thermometers was false and misleading since the thermometers were not accurate within 2/10 of a degree at the degrees of temperature designated in the labeling.

PLEA: Guilty.

DISPOSITION: 6-17-59. Corporation—\$2 fine; individual—\$200 fine, 3 months suspended jail sentence, and probation for 48 hours.

**5793. Clinical thermometers (oral).** (F.D.C. No. 41699. S. No. 38-894 P.)

QUANTITY: 98 thermometers individually boxed at San Francisco, Calif.

**SHIPPED:** 12-11-57, from Watertown, N.Y., by Faichney Instrument Corp.

**LABEL IN PART:** (Box) "Oral Type Fever Thermometer Faichney's Signal Thermometer," (etched on thermometer) "Conn G. Faichney Watertown, N.Y."

**ACCOMPANYING LABELING:** Leaflet entitled "Certificate of Accuracy."

**RESULTS OF INVESTIGATION:** Examination of 18 thermometers showed that 3 failed to meet the standard of accuracy specified in CS1-52, issued by the National Bureau of Standards of the Department of Commerce, when tested as described in CS1-52.

**LIBELED:** 5-13-58, N. Dist. Calif.

**CHARGE:** 501(c)—when shipped, the quality of the article fell below that which it purported and was represented to possess since it did not give accurate readings.

**DISPOSITION:** 2-27-59. Default—destruction.

**5794. Rubber prophylactics.** (F.D.C. No. 42242. S. Nos. 22-291 P, 22-293 P, 22-295/7 P.)

**QUANTITY:** 7 ctns., containing a total of 346 gross; 3 drums, containing a total of 1,000 gross; 9 drums, containing a total of 3,000 gross; and 17 drums, containing a total of 5,666 gross, at Kansas City, Mo.

**SHIPPED:** Between 7-1-58 and 10-2-58, from Carolina, Puerto Rico, by De Caribe Rubber Co.

**RESULTS OF INVESTIGATION:** Examination showed that from 1.3 to 2 percent of the article was defective in that it contained holes.

**LIBELED:** 10-23-58, W. Dist. Mo.

**CHARGE:** 501(c)—the quality of the article, when shipped, fell below that which it purported to possess.

**DISPOSITION:** The M & M Rubber Co., claimant, having consented to the entry of a decree, judgment of condemnation was entered on 11-21-58, and the article was ordered released under bond for salvaging under the supervision of the Food and Drug Administration. It appearing impractical to process the 7-carton lot, and, the claimant having consented, a supplemental decree was entered on 11-25-58, ordering the article in the 7-carton lot destroyed.

Thereafter, the articles in the drums were retested and the unfit portion was destroyed.

#### DRUGS FOR VETERINARY USE

**5795. Blue Seal All-Mash Grow and Lay Medicated.** (F.D.C. No. 42210. S. No. 7-964 P.)

**QUANTITY:** 80 100-lb. bags at Jonesboro, Maine.

**SHIPPED:** 8-26-58, from Richford, Vt., by H. K. Webster Co.

**LABEL IN PART:** "Blue Seal All-Mash Grow and Lay Medicated \* \* \* Active Drug Ingredient: Glycarbylamide (4,5-imidazoledicarboxamide) 0.002% \* \* \* Manufactured by H. K. Webster Company Lawrence, Mass. 6602 Richford, Vermont."

**LIBELED:** 10-1-58, Dist. Maine.

**CHARGE:** 501(c)—when shipped, the quality of the article fell below that which is purported and was represented to possess since the article contained sulfaquinoxaline in place of glycarbylamide; 502(a)—the label statement

"Glycarbylamide \* \* \* 0.002%" was false and misleading; and 502(e) (2)—the label of the article failed to bear the common or usual name of each active ingredient contained therein since the presence of sulfaquinoxaline was not declared.

DISPOSITION: 11-18-58. Default—destruction.

**5796. Stockade procaine penicillin (veterinary).** (F.D.C. No. 42232. S. No. 22-331 P.)

QUANTITY: 41 10-lb. bags at Kansas City, Mo.

SHIPPED: 7-21-58, from Pittsburg, Kans., by Harvest Brand, Inc.

LBELED: On or about 10-27-58, W. Dist. Mo.

CHARGE: 501(c)—when shipped and while held for sale, the strength of the article differed from, and its purity and quality fell below, that which it was represented to possess (the article was represented to contain .7938 grams of procaine penicillin (equivalent to .445 grams of crystalline penicillin) per pound, whereas the article contained less than the represented amount of procaine penicillin per pound); and 502(a)—the label statement "Active Drug Ingredient: .7938 gms. or 793,800 units of Procaine Penicillin per pound. (Equivalent to .445 gms. crystalline penicillin G Master Standard)" was false and misleading.

DISPOSITION: 1-15-59. Default—destruction.

#### DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS\*

**5797. Berkeley Springs water.** (F.D.C. No. 41979. S. No. 4-831 P.)

QUANTITY: 42 cases, 12 1-qt. btls. each, at Bethesda, Md.

SHIPPED: 8-8-58, from Berkeley Springs, W. Va., by Berkeley Club Bottling & Mfg. Co., Inc.

LABEL IN PART: (Btl.) "Berkeley Springs Water \* \* \* Bottled by the Manufacturers of the Famous Berkeley Club Ginger Ale Berkeley Springs, W. Va."

LBELED: 9-10-58, Dist. Md.

CHARGE: 502(a)—the label on the bottles of the article, when shipped, contained false and misleading representations that the article was effective in the treatment of rheumatism, gout, diabetes, liver disorders, stomach disorders, and for providing youthful vigor.

DISPOSITION: 10-31-58. Default—destruction.

**5798. Alfalfa leaf meal, alfalfa tablets, and alfalfa tea.** (F.D.C. No. 42193. S. Nos. 21-870/2 P.)

QUANTITY: 5 50-lb. bags of *alfalfa leaf meal*, 72 100-tablet btls., 22 200-tablet btls. and 120 500-tablet btls. of *alfalfa tablets*, together with 50,000 *alfalfa tablets* in bulk, and 120 12-oz. ctns. of *alfalfa tea*, at Kansas City, Mo., in possession of Houston Boyd Co.

SHIPPED: 10-1-57, from St. Marys, Kans.

LABEL IN PART: (Bag) "Dehydrated Alfalfa Meal \* \* \* Guaranteed Analysis: Protein not less than 20.0% Fat not less than 1.5% Fiber not more than 22.0% Nitrogen-free extract 27.0% (with "20%" over stamped in red)"; (btl.) "Nature's GREEN FOOD CONCENTRATE ALFA TABS Made from

\*See also Nos. 5783-5785, 5788, 5789, 5791, 5792, 5795.



Choice Leaves of Alfalfa \* \* \* 5 Grain Tablets Houston Boyd Company"; (ctn.) "Nature's GREEN FOOD CONCENTRATE INSTANT ALFA TEA Made from Choice Leaves of Alfalfa.

ACCOMPANYING LABELING: Leaflets entitled "Winter Winds Bring Calls for Alfalfa—Why?"

RESULTS OF INVESTIGATION: The *alfalfa leaf meal* was shipped in bulk as described above, and upon receipt at Kansas City, Mo., was used by the consignee in the manufacture and packaging of the tablets and tea.

The above-mentioned leaflets were printed at Kansas City Mo., and used by the consignee in promoting the sale of the articles.

LIBELED: On or about 9-17-58, W. Dist. Mo.

CHARGE: 502(a)—the labeling accompanying the articles, while held for sale, contained false and misleading representations that the articles were an adequate and effective treatment for arthritic and rheumatic pains.

DISPOSITION: 10-29-58. Default—destruction.

5799. Yerba maté. (F.D.C. No. 42172. S. Nos. 29-856/8 P.)

QUANTITY: 401 labeled boxes, each containing 30 bags, and 168 unlabeled boxes, each containing 22 bags, at New York, N.Y.

SHIPPED: Between 1-8-58 and 7-11-58, from Bristol, Pa.

LABEL IN PART: (Box) "Cassera Brand South American Maté \* \* \* 30 bags (double size) Net Weight 3½ Ounces D. Turet Importer."

ACCOMPANYING LABELING: Folders entitled "The Wonderful Story of Yerba Maté"; leaflets entitled "A Good Suggestion" and "Regular Users of Yerba Maté"; testimonial leaflets entitled "Some Opinions"; and wallet-type reply envelopes.

LIBELED: 9-22-58, S. Dist. N.Y.

CHARGE: 502(a)—the labeling accompanying the article, while held for sale, contained false and misleading representations that the article was an adequate and effective treatment for producing exhilaration and relief from fatigue, stomach acidity, indigestion and constipation; is a heart tonic; a diuretic; exciting the brain to increased mental activity and capacity; stimulating organs of nutrition; comforting the mind and dispelling weariness, insomnia, cerebral erethism, headache, migraines, other cephalalgias, debility of neurasthenia, migraine, and dyspepsia; counteracting depression of alcoholic debauching; gout, stomach disorders, nerve disorders, and others.

DISPOSITION: 10-27-58. Default—destruction.

5800. Kelp-ettes (sea kelp). (F.D.C. No. 41911. S. No. 11-326 P.)

QUANTITY: 105 100-lb. drums of sea kelp, and 756 500-tablet unlabeled btl., and 142 500-tablet btl., 21 1,000-tablet btl., and 17 2,000-tablet btl., labeled as described below, at Hobart, Ind., in possession of Nelson's Natural Foods.

SHIPPED: 12-6-57, from San Pedro, Calif.

LABEL IN PART: (Btl.) "Nelson's \* \* \* 5 Grain Tablets KELP-ETTES \* \* \* A Pure Vegetable Sea Food containing an abundance of SAFE NATURAL IODINE Plus other Minerals, trace elements, organic compounds and vitamins pressed from pure Ocean Kelp. No other substance added in making the tablets \* \* \* Packed and Distributed by Nelson's Natural Foods \* \* \* Battle Creek, Michigan \* \* \* Hobart, Indiana."

ACCOMPANYING LABELING: Leaflets entitled "Hunger in the Midst of Plenty."

RESULTS OF INVESTIGATION: The tablets in the bottles were repackaged by the dealer from bulk stock which had been shipped as described above.

The above-mentioned leaflets were printed locally for the dealer.

LIBELED: 7-7-58, N. Dist. Ind.

CHARGE: 502(a)—the labeling accompanying the article in bulk and as repackaged, while held for sale, contained false and misleading representations that the article was effective to prevent and treat falling hair, stomach trouble, kidney disfunction, gland trouble, premature old age, tiredness, cold hands and feet, slowing thinking, premature grey hair, ulceration, tuberculosis, rickets, acidosis, excessive weight, constipation, concretions in the body, arthritis, hardening of the arteries, cataract, sinus and catarrhal conditions, impurities of the blood; and was effective to promote proper heart action, vitality and longer life, stamina and endurance, sound bones and teeth, digestion, mental ability, hormone function, supple joints, liver and gall bladder functions, nerve relaxation, enzyme production, beauty and good disposition, healthy nerves, and tissue respiration.

DISPOSITION: 11-5-58. Consent—claimed by Nelson's Health Foods, Hobart, Ind., and relabeled.

**5801. Saffocil capsules.** (F.D.C. No. 41883. S. No. 34-251 P.)

QUANTITY: 2 bulk ctns., each containing 5,000 capsules, and 44 72-capsule btl., at Norristown, Pa., in possession of Plymouth Vitamin Products.

SHIPPED: 1-31-58, from Detroit, Mich.

LABEL IN PART: (Btl.) "Saffocil Formula 537 Unsaturated Fatty Acids with Pyridoxine HCl \* \* \* Provides supplemental essential unsaturated fatty acids to daily diet. Daily ration of three capsules provides: Linoleic Acid 2595 Mg. Oleic Acid 660 Mg. Palmitic Acid 135 Mg. Stearic Acid 60 Mg. Mixed Tocopherols .828 Mg. (preceding from 3450 Mg. of Safflower Oil) and 9 Mg. of Vitamin B<sub>6</sub>. The minimum daily requirements for B<sub>6</sub> and the need for unsaturated fatty acids and mixed tocopherols in human nutrition have not been established. 72257 Dist. by Plymouth Vitamin Products Plymouth Meeting, Pa."

ACCOMPANYING LABELING: Leaflets entitled "Plymouth Nutritional Review - Published for the Information and Knowledge of our Customers" and reprints of an article appearing in the July 1, 1957 issue of Drug Trade News entitled "Sees Essential Fatty Acid Lack Causing Degenerative Disease."

RESULTS OF INVESTIGATION: The article in the bottles was repackaged and labeled by the dealer, and the above-mentioned leaflets and reprints were used by the dealer in promoting the sale of the article.

LIBELED: 6-24-58, E. Dist. Pa.

CHARGE: 502(a)—the labeling accompanying the article, while held for sale, contained false and misleading representations that the article, when used as directed, would prevent, and was an adequate and effective treatment for, atherosclerosis, heart disease, artery disease, nephrosis, angina pectoris, high blood pressure, obesity, and glandular dyscrasias; and the following statements on the bottle label, namely, "Provides supplemental essential unsaturated fatty acids to daily diet" and "the need in human nutrition for un-

saturated fatty acids \* \* \* have not been established" were false and misleading since the two statements are contradictory.

DISPOSITION: 11-19-58. Default—destruction.

**5802. Super Nucleol capsules.** (F.D.C. No. 41464. S. Nos. 15-467/72 P.)

QUANTITY: 37½ doz. 25-capsule btl., 22¼ doz. 50-capsule btl., and 27 doz. 100-capsule btl. at Cleveland, Ohio.

SHIPPED: 4-18-57 and 1-10-58, from New York, N. Y., by American Vitamin Products, Inc.

LABEL IN PART: "SUPER NUCLEOL High Potency Vitamins A, B-1, B-2, C, D, Plus Iron and Other Trace Minerals, with Additional Vitamins including the Red Vitamin B-12 and Citrus Bioflavonoids Complex \* \* \* Food Supplement."

ACCOMPANYING LABELING: Placards headed "Doctors Report New Cases Daily Be Prepared against Asiatic Flu \* \* \* Super Nucleol."

RESULTS OF INVESTIGATION: The placards were placed in retail stores of the consignee by representatives of the shipper.

LIBELED: 4-2-58, N. Dist. Ohio.

CHARGE: 502(a)—when shipped and while held for sale, the labeling of the article contained false and misleading representations that the article was effective for preventing Asiatic "flu," combating the severity of Asiatic "flu" and overcoming a condition of undue fatigue, loss of normal pep and energy, lack of appetite, constipation, digestive upsets, nervous irritability, and generalized malaise or debility, especially in persons who are in their later life.

DISPOSITION: 11-25-58. Consent—claimed by American Vitamin Products, Inc., and relabeled.

**5803. Saf-Flower Seed Oil.** (F.D.C. No. 42222. S. No. 41-287 P.)

QUANTITY: 2 cases, 24 8-oz. btl. each, and 9 cases, 12 1-pt. btl. each, at Seattle, Wash.

SHIPPED: 3-31-58, from Los Angeles, Calif., by Kahan & Lessin Co.

LABEL IN PART: (Btl.) "Cholesterol Lowering Factor Hain Saf-Flower Seed Oil Contains 92% Unsaturated Fatty Acid and Natural Tocopherols (Vitamin E) \* \* \* Excellent For salads and Fine Cooking \* \* \* Distributed by Hain Pure Food Company, Inc., Los Angeles, Calif."

ACCOMPANYING LABELING: Placards entitled "Fight Against Heart Disease" and "Here Now."

LIBELED: 10-13-58, W. Dist. Wash.

CHARGE: 502(a)—the labeling of the article, when shipped, contained false and misleading representations that the article was an adequate and effective treatment for reducing cholesterol levels in blood and arteries and overcoming heart disease.

The article was alleged also to be misbranded under the provisions of the law applicable to foods as reported in notices of judgment on foods.

DISPOSITION: 12-31-58. Default—destruction.

**5804. Inhepat tablets.** (F.D.C. No. 42276. S. Nos. 31-869/70 P.)

QUANTITY: 400 100-tablet btl., 6 500-tablet btl., and 2 drums, each containing about 47,422 tablets, at New York, N.Y., in possession of Brown Drug Co.



**SHIPPED:** The tablets in the drums were shipped on 7-23-58 and 7-31-58, from Fort Erie, Canada, and the tablets in the bottles were shipped in bulk on 8-12-57 and 8-30-57, from Montreal, Canada.

**LABEL IN PART:** (Btl.) "INHEPAT Each e.c. tablet contains: Pancreatin 100 mg. Pancrein 50 mg. Sodium Glycocholate 30 mg. Sodium Taurocholate 30 mg. Sodium Dehydrocholate 20 mg. Hepatin\* 50 mg. Cascara Sagrada 10 mg. Vitamin B<sub>1</sub> 0.1 mg. Riboflavin 0.1 mg. \*Liver Extract 1:5," (drum) "Special Formula Pancrepatine Pills \* \* \* Each sugar coated pill contains: Pancreatin 100 mg. Desiccated whole pancreas 50 mg. Sodium glycocholate 30 mg. Sodium taurocholate 30 mg. Sodium dehydrocholate 20 mg. Hepatin\* 50 mg. Antipyrine 25 mg. Cascara Sagrada 10 mg. Vitamin B<sub>1</sub> 0.1 mg. Riboflavin 0.1 mg. \*Liver extract 1:5."

**ACCOMPANYING LABELING:** Cards designated "5 Points to Observe in Inhepat" and leaflets designated "Treating the Diabetic Without the Needle" and "In Diabetes Mellitus."

**RESULTS OF INVESTIGATION:** The tablets in the bottles were repackaged from the above-mentioned bulk shipment from Montreal, Canada, and labeled by the Brown Drug Co.

The above-mentioned accompanying labeling was printed at New York, N.Y., from formats furnished by the Anglo-French Drug Company, Ltd., of Montreal, Canada.

**LIBELED:** 11-13-58, S. Dist. N.Y.

**CHARGE:** 502(a)—the labeling accompanying the articles, while held for sale, contained false and misleading representations that the articles were an adequate and effective treatment for diabetes mellitus.

**DISPOSITION:** 12-24-58. Consent—claimed by Brown Drug Co. and relabeled.

**5805. Pollen Gold, The Wonder Food and Pollen Gold Food Supplement.** (F.D.C. No. 42277. S. Nos. 41-583/4 P.)

**QUANTITY:** 72 boxes, consisting of various flavors of *Pollen Gold, The Wonder Food* and 45 boxes, of *Pollen Gold Food Supplement*, at Portland, Oreg.

**SHIPPED:** Between 8-27-58 and 9-26-58, from Wenatchee, Wash., by L. C. Antles, Fruit Tree Pollen Supplies Co.

**LABEL IN PART:** (Box) "L. C. Antles Pollen Gold The Wonder Food Contents Honey, Pollen, Dry Skim Milk, Flavoring Net Wt. 8 oz." and "L. C. Antles Pollen Gold Food Supplement Contents Approximately Half Pollen, Half Honey \* \* \* Capsules Net Weight 7 Ounces."

**ACCOMPANYING LABELING:** Leaflets entitled "Pollen Gold—A Wonderful Food Promotion and Clarification"; "Pollen Analysis \* \* \* The Chemical Composition and Nutritional Value of Pollens"; "L. C. Antles Pollen Gold (Pollen Nectar)"; "The Value of Pollen as a Food For Bees The Bee World November, 1940"; "Pollen Analysis The Chemical Composition and Nutritional Value of Pollens Collected by Bees"; "Laucks Testing Laboratories Report Description Date Number"; "L. C. Antles Pollen Gold Pollen Nectar"; and "L. C. Antles Pollen Gold Pollen Nectar \* \* \* L. C. Antles Supply Co."

**LIBELED:** 11-12-58, Dist. Oreg.

**CHARGE:** 502(a)—the labeling of the articles, when shipped, contained false and misleading representations that the articles were capable of promoting longevity, youthfulness, laxation and sleep; repairing worn-out tissues, in-

creasing sexual potency, checking the appetite, bringing about a loss of body weight, soothing the stomach, relieving coughs, and the pain of arthritis and nervousness, treating hay fever, healing burns, preventing fatigue and aiding digestion.

The libel alleged also that the articles were misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 1-2-59. Consent—claimed by L. C. Antles and relabeled.

**5806. Trifosan tablets.** (F.D.C. No. 42289. S. No. 28-362 P.)

QUANTITY: 1 bulk drum, containing 50,000 tablets, and 102 btl. of tablets, at Birmingham, Ala., in possession of Veltex Co.

SHIPPED: 3-5-57, from Philadelphia, Pa.

LABEL IN PART: (Btl.) "Trisfosan Tablets \* \* \* An Herbal Compound with Potassium Iodide especially adapted as an aid in helping to reestablish nutritive processes. \* \* \* Each Tablet Contains: Powd. Ext. Trifolium 1 grain, Powd. Ext. Stillingia Root  $\frac{1}{4}$  grain Potassium Iodide  $\frac{1}{2}$  grain Powd. Ext. Lappa  $\frac{1}{2}$  grain Powd. Ext. Phytolacca  $\frac{1}{2}$  grain Powd. Ext. Berberis Aquifolium  $\frac{1}{2}$  grain Powd. Ext. Xanthoxylum  $\frac{1}{8}$  grain Powd. Ext. Echinacea Root  $\frac{1}{4}$  grain Powd. Ext. Sarsaparilla Root  $\frac{1}{8}$  grain With Oil anise and Powd. Ext. Licorice Root as flavors \* \* \* Take one tablet three times daily \* \* \* The Veltex Company Distributors—Birmingham, Alabama."

ACCOMPANYING LABELING: Pamphlet designated "Catalogue No. 106-CN \* \* \* Veltex Company Manufacturing Chemists."

RESULTS OF INVESTIGATION: The bottle of tablets were repacked and labeled by the Veltex Co. from the tablets contained in the bulk drum described above.

LIBELED: 11-7-58, N. Dist. Ala.

CHARGE: 502(a)—the labeling of the article, while held for sale, contained false and misleading representations that the article was effective for overcoming digestive and nutritive disturbances, boils, and "poor blood."

DISPOSITION: 11-25-58. Consent—claimed by the Veltex Co. and relabeled.

**5807. Lotion-Jel.** (F.D.C. No. 42055. S. No. 14-827 P.)

QUANTITY: 336 tubes at Indianapolis, Ind.

SHIPPED: 5-15-58, from Cincinnati, Ohio, by Grandpa Soap Co.

LABEL IN PART: "Dent's Lotion-Jel \* \* \* C. S. Dent, Cincinnati 2, O."

RESULTS OF INVESTIGATION: Examination showed that the article contained 4.75 percent benzocaine (Ethyl Aminobenzoate) in a jel-type base.

LIBELED: 8-12-58, S. Dist. Ind.

CHARGE: 502(a)—the label of the article and a display card accompanying the article, when shipped, contained false and misleading representations that the article was an adequate and effective treatment for any gum discomfort, gum soreness, gum boils, denture irritations, and similar irritations of the gums.

DISPOSITION: 1-26-59. Default—destruction.

**5808. Buticaps capsules.** (F.D.C. No. 38723. S. Nos. 20-060/1 M.)

QUANTITY: 204 pkgs. at Washington, D.C.

SHIPPED: 9-8-55, from Los Angeles, Calif., by Buticaps, Inc.

LABEL IN PART: (Pkg.) "Buticaps the internal skin conditioner For Normal or Dry Skin 30 Capsules \* \* \* A dietary supplement recommended as an aid

in skin conditioning containing the multiple vitamin group, certain Lipotropic agents and Vitamins H, H-1 and (F)—for the treatment of a deficiency of one or more of the following ingredients: Each capsule contains: Vitamin A Palmitate 25,000 USP Units Free Fatty Acids of Linseed Oil 20 Milligrams Principally Linoleic and Linolenic Acids, (Vitamin F) Choline Bitartrate 40 Milligrams Inositol 20 Milligrams dl-Methionine 15 Milligrams Betaine Monohydrate 10 Milligrams Vitamin B-12 USP (Crystalline) 2 Micrograms Folic Acid 100% USP 0.5 Milligram Thiamine Mononitrate 10 Milligrams Pyridoxine Hydrochloride 1 Milligram Riboflavin 6 Milligrams Niacinamide 20 Milligrams Vitamin D (Irradiated Ergosterol) 500 USP Units Calcium Pantothenate 20 Milligrams Ascorbic Acid 50 Milligrams Biotin (Vitamin H) 0.12 Milligram Para-amino Benzoic Acid 5 Milligrams (Bacterial Vitamin H-1) Mixed Tocopherols 5 Milligrams Plus Vitellin (Lecithin from Soya Bean) 25 Milligrams" and (pkg.) "Buticaps the internal skin conditioner For Oily Skin 30 Capsules \* \* \* A dietary supplement recommended as an aid in skin conditioning containing the multiple vitamin group, certain Lipotropic agents and Vitamins H, H-1 and (F)—for the treatment of a deficiency of one or more of the following ingredients: Each capsule contains: Pyridoxine Hydrochloride 5 Milligrams Free Fatty Acids of Linseed Oil 10 Milligrams Principally Linoleic and Linolenic Acids, (Vitamin F) Choline Bitartrate 40 Milligrams Inositol 40 Milligrams dl-Methionine 30 Milligrams Betaine Monohydrate 10 Milligrams Vitamin B-12 USP (Crystalline) 2 Micrograms Folic Acid 100% USP 0.5 Milligram Thiamine Mononitrate 10 Milligrams Vitamin A—Palmitate 15,000 USP Units Riboflavin 6 Milligrams Niacinamide 20 Milligrams Vitamin D (Irradiated Ergosterol) 500 USP Units Calcium Pantothenate 20 Milligrams Ascorbic Acid 50 Milligrams Biotin (Vitamin H) 0.16 Milligram Para-amino Benzoic Acid 5 Milligrams (Bacterial Vitamin H-1) Mixed Tocopherols 5 Milligrams Plus Vitellin (Lecithin from Soya Bean) 25 Milligrams."

ACCOMPANYING LABELING: Booklet entitled "here's how \* to promote \* to sell \* to profit with Buticaps" and leaflets entitled "Buticaps."

LIBELED: 11-30-55, Dist. Columbia; libel amended, 9-17-56.

CHARGE: 502(a), when shipped,

(1) the labeling contained false and misleading representations that the article was an adequate and effective treatment for dry or oily skin, unsightly blemishes of acne and other skin disorders in the adolescent, and skin conditions due to overindulgence; was a revolutionary new approach to skin conditioning; would aid in prematurely "aged skin"; was effective in retaining the normal moisture and stabilizing the oil balance of the skin; had beneficial effects on the eyes, hair, scalp, teeth and gums; would bring nourishment to a starving complexion and aid in carrying away wastes which cause unsightliness; and was an effective treatment for scaly or cracked skin, enlarged pores, unnecessary wrinkles and that tired look;

(2) the designations "Vitamins, H, H-1 and (F)" appearing on the package labels were false and misleading since use of such designations were obsolete and no longer had any recognized use and implied promise of benefit from vitamins with which the user was not familiar;

(3) the label designation "Plus Vitellin (Lecithin from Soya Bean)" was false and misleading since "Vitellin" is not lecithin from soy beans but is the common or usual name for a protein prepared from yolk of eggs; and



(4) the name "*Buticaps*" was false and misleading since it represented, suggested, and implied that the article would beautify the skin of the user whereas it would not beautify the skin of the user.

**DISPOSITION:** *Buticaps, Inc.*, Los Angeles, Calif., appeared as claimant and admitted the material allegations in the libel except the claimant denied that the name "*Buticaps*" was false and misleading.

Thereafter, the Government filed a motion for judgment on the pleadings on the ground that all material facts had been admitted by the answer. On 1-25-57, the district court granted the Government's motion and ordered that the article be released for relabeling under the supervision of the Department of Health, Education, and Welfare. On 2-28-57, the claimant filed a motion to relabel and requested the court to specify that there had been no judicial determination that the name "*Buticaps*" did not comply with the statute and that the name need not be changed. The claimant's motion was denied by the court on 4-8-57.

Thereafter, on 5-21-57, the court having determined that because of the claimant's insistence upon the use of the name "*Buticaps*," further efforts to relabel would be fruitless, the article was ordered destroyed. The claimant then appealed to the United States Court of Appeals for the District of Columbia which reversed the decision of the trial court in the following opinion on 1-30-58 (252 F.2d 634) :

PER CURIAM: "The libel in this case was filed to condemn certain articles of drug (a claimed skin conditioner) in accordance with the Federal Food, Drug and Cosmetic Act.<sup>1</sup> It was claimed that the articles were misbranded within the meaning of said Act in that: (1) as alleged in paragraph 3 of the libel a leaflet entitled '*Buticaps*' enclosed in each package, and a booklet entitled 'here's how \* to promote \* to sell \* to profit with *Buticaps*' contained statements which were false and misleading; and (2) as alleged in paragraph 4 of the libel the aforementioned articles were further misbranded in that the designations of certain vitamins and proteins appearing on the package labels were false and misleading.

"Thereafter, the libel was amended by adding paragraph 3(a) to allege that the name '*Buticaps*' on the package labels, leaflet and booklet represents and implies that the articles will beautify the skin of the user, which is false and misleading since the articles will not beautify the skin of the user.

"After answer by libelee admitting the allegations in paragraphs 3 and 4 of the libel but denying the allegations in paragraph 3(a) as to the use of the word '*Buticaps*,'<sup>2</sup> the Government filed motion for judgment on the pleadings. This motion was not opposed but, in the answer thereto, libelee [claimant] urged: 'If this Motion is granted, claimant's pleading with regard to the name '*Buticaps*' must be taken as true.'

"The District Court filed a memorandum announcing that it would grant the motion for judgment on the pleadings but would exercise its discretion in not ordering the articles destroyed, as it had a right to do,<sup>3</sup> and would release the seized articles for relabeling. The court's memorandum contained the following language:

\* \* \* Provided, however, that the claimant post a good and sufficient bond to insure compliance with the statute and that relabeling is done under the supervision of an officer or employee duly designated by the Secretary of the Department of Health, Education and Welfare, as the statute provides, the expenses of such supervision to be paid by the claimant. The Court regards these provisions as mandatory.

Order accordingly.

<sup>1</sup> 21 U.S.C.A. § 301-392 (1952)

<sup>2</sup> It was claimed by libelee in its answer that the name was "neither false nor misleading since it is a coined word which has no meaning aside from the meaning given it by naming this product."

<sup>3</sup> 21 U.S.C.A. § 334(d)

"Thereupon, on February 19, 1957, the court ordered that judgment on the pleadings be entered in favor of plaintiff [libelant].

"On February 28, 1957, libelee moved the court for an order directing that the condemned articles be delivered to libelee and requesting that the court specify, pursuant to the judgment on the pleadings, that the statute was found to have been violated in the following manner and only in the following manner:

"(1) Misbranding in reference to a leaflet entitled 'Buticaps,' enclosed in each package of the condemned article;

"(2) Misbranding in reference to two designations appearing on the label of the seized articles.

"Libelee asked that the court 'further specify that the seized articles must now be brought into compliance with the Federal Food, Drug and Cosmetic Act \* \* \* by appropriate relabeling but that, pursuant to the aforesaid judgment, there has been no judicial determination in this action that the name "Buticaps" does not comply with the statute, which name need, therefore, not be changed under the judgment entered heretofore in this action.'

"The Government's reply to the motion stated that the position of the *Department of Health, Education and Welfare* was that the name 'Buticaps' is false and misleading, and that it would be a violation of the statute to allow relabeling under that name. Thereupon, on May 21, 1957, the court entered its order reciting, among other things, that because of libelee's insistence upon the use of the name 'Buticaps,' further efforts to relabel would be fruitless; and the court directed that the articles seized be destroyed by the United States Marshal. This appeal followed:

"We think this ruling of the District Court was erroneous. The judgment on the pleadings was limited, of necessity, to the admitted facts. We believe that the refusal of the Department of Health, Education and Welfare to allow relabeling unless the word 'Buticaps' was eliminated was unauthorized, and that libelee was entitled to a *judicial* hearing and ruling on the question of the alleged misuse of the word. See *Ewing v. Mytinger & Casselberry*, 339 U.S. 594, 70 S. Ct. 870, 94 L. Ed. 1088 (1950).

"We agree that as the Government contends, '[b]y violating the law and introducing a misbranded drug into interstate commerce, the owner of the article, after there has been a judicial determination that the article violates the law, loses any *right* to repossess his property' and that '[h]e regains the property upon such terms and conditions as to the trial court seem just and proper, within the confines of the powers conferred by Section 304(d) of the Act' [21 U.S.C.A. § 334(d)]. But the terms and conditions are to be fixed by the *court* and not by the Department of Health, Education and Welfare. Libelee is entitled to judicial due process.

"It is no answer, as urged by libelant, to say that the name 'Buticaps' itself implies that the article will impart beauty. It may be that, on hearing, the court, on evidence, could determine that the use of the name 'Buticaps' is misleading. As to this, we express no opinion.

"Accordingly, the judgment of the District Court is reversed; and the case is remanded to that court, either to proceed to the judgment of relabeling, insofar as the admitted violations are concerned, or, if the court be so advised, to re-open the case to determine the issue as to the use of the word 'Buticaps.'<sup>4</sup>

"Reversed and remanded."

Thereafter, on 6-4-58, the claimant filed a motion for judgment of relabeling. On 6-6-58, the trial court vacated its order of 5-21-57, and ordered that the cause proceed to judgment of relabeling as to admitted violations, or if the court be so advised, that it be reopened to determine the issue as to the use of the word "*Buticaps*." On the same day, the Government filed such a motion to reopen, and the Government's motion to reopen was granted on 10-24-58 and claimant's motion to relabel was denied.

<sup>4</sup> It is noted that libelant, at the hearing on the motion of libelee to relabel the condemned articles, orally moved that the case be reopened for the purpose of trial on "the merits of that one issue."



On 1-6-59, the claimant asserting that it was financially unable to prosecute further its claim to the article, and the claimant having discontinued the manufacture of the article known as "*Buticaps*," it was stipulated and agreed between the Government and the claimant that the claimant's claim be withdrawn and that the article under seizure be destroyed, and accordingly the article was ordered condemned and destroyed on 1-22-59.

**5809. Sugar-chek (urine sugar test tape) (2 seizure actions).** (F.D.C. No. 42177, 42178. S. Nos. 14-647/8 P.)

**QUANTITY:** 426 display ctns., each ctn. containing 36 envelopes, and each envelope containing 1 piece of treated tape (paper) in a sealed package and 1 leaflet, at Chicago and Forest Park, Ill.

**SHIPPED:** During 1957, from St. Louis, Mo., to Springfield, Ill., from where it was re-shipped to Chicago and Forest Park, Ill.

**LABEL IN PART:** (Envelope) "Sugar-Chek."

**ACCOMPANYING LABELING:** Leaflet entitled "What is a Diabetic?"

**LIBELED:** 9-8-58, N. Dist. Ill.

**CHARGE:** 502(a)—while held for sale, the labeling of the article contained false and misleading representations that the article was effective for detecting the presence of sugar in the urine, and thus acting as a diagnostic sign of diabetes.

**DISPOSITION:** 10-30-58 and 10-31-58. Default—destruction.

**5810. Magic copper band.** (F.D.C. No. 42287. S. No. 21-678 P.)

**QUANTITY:** 749 devices, each in a plastic box, at Lincoln, Nebr., in possession of M. J. Co.

**SHIPPED:** 3-18-58, from Providence, R.I.

**LABEL IN PART:** (Label insert in box) "Here is Your Magic Copper Band"; (back of label) "Handy Order Form Mail to: Magic Copper Band \* \* \* Lincoln, Nebr."

**RESULTS OF INVESTIGATION:** Examination showed that the article was a copper-colored metal band  $\frac{1}{4}$  inch in width, and, when open, about 6 inches in length.

The above-described label inserts were printed locally for the dealer.

**LIBELED:** 11-13-58, Dist. Nebr.

**CHARGE:** 502(a)—while held for sale, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for relief from the pains of arthritis and rheumatism.

**DISPOSITION:** 12-17-58: Default—destruction.

**5811. Exercycle devices.** (F.D.C. No. 40644. S. No. 68-225/6 M.)

**QUANTITY:** 24 devices at Kansas City, Mo.

**SHIPPED:** Between 6-17-57 and 8-26-57, from Hartford, Conn., by the Exercycle Corp.

**ACCOMPANYING LABELING:** Leaflets designated "Feeling Like A Million" and a pamphlet entitled "Organizational Bulletin No. 119."

**RESULTS OF INVESTIGATION:** The device consisted of a framework resembling a wheelless bicycle equipped with an electric motor which produced motion of the pedals, seat, and handlebars.

**LIBELED:** 9-19-57, W. Dist. Mo.



**CHARGE:** 502(a)—the labeling accompanying the article, when shipped, contained false and misleading representations that the device was effective for providing a daily rejuvenating treatment, streamlining one's figure, increasing one's powers of endurance, improving one's chances against certain types of heart attacks, improving the body metabolism, strengthening the heart, keeping the joints flexible, improving the digestion and elimination, and equalizing the blood pressure; overcoming stagnation of blood circulation and body metabolism, breathlessness, circulatory disorders, lack of strength, pep, and energy, overweight, and premature old age; making one into a "new person," enabling one within 10 days to feel younger, and in 30 days enabling one to stand taller, feel lighter, look healthier, eat heartier, and sleep more soundly; providing positive weight control by "burning up" excess calories before they turn into dangerous fat; enabling a person past 60 to have the body and stamina of a young healthy man of 35, with high energy, strong heart, normal blood pressure, regular elimination, quiet nerves, lungs in top shape, erect posture, and muscles and joints flexible and pliable, with the feel of a youngster and the working ability of "the proverbial horse"; helping the heart by keeping the heart muscles from becoming soft, flabby, and weak; overcoming a tendency to be easily winded while climbing stairs, lifting heavy objects, or engaging in strenuous work; alleviating any disease, ailment, or injury which has affected the conditions of the shoulders, arms, back, legs, stomach, pelvic region, chest, and other parts of the body; acting as a "heart-conditioning, fat-consuming and muscle-toning" exercise; preventing the "chronic middle-aged ailments" such as digestive upsets, heartburn, acidosis, postural diabetes, constipation, headaches, neurasthenia, fatty degeneration of the heart, breathlessness, chronic fatigue, piles, "heart failure," kidney disorders, chronic ailments, and sudden death; preventing high blood pressure, albuminuria, glycosuria, cerebral hemorrhages, angina pectoris, and Bright's disease; preventing one from being a hopeless cripple due to arthritis; enabling a diabetic to cut down the necessary daily dose of insulin; overcoming the after-effects of infantile paralysis; overcoming serious spinal injury and its after-effects; overcoming convulsions in persons who would otherwise have convulsions at frequent intervals; overcoming high blood pressure; overcoming low blood pressure, and overcoming stiff and swollen joints.

**DISPOSITION:** 11-12-58. Consent—claimed by Exercycle Corp. and relabeled.

**5812. Vibro-Massage unit.** (F.D.C. No. 42203. S. No. 29-637 P.)

**QUANTITY:** 16 devices at Dallas, Tex.

**SHIPPED:** 6-24-57 and 8-22-57, from Lohrville, Iowa, by Giro Power Mfg. Co.

**LABEL IN PART:** (Metal plate on device) "Vibro-Massage Unit \* \* \* Model MV 6."

**ACCOMPANYING LABELING:** Leaflets entitled "Magic Belt Massage."

**RESULTS OF INVESTIGATION:** The device consisted of a stand or base into which a long metal tube with an electric motor on top was mounted. A long web belt was attached to each end of the motor and when the motor was switched on the belt would vibrate. The motor was enclosed in a protective and decorative covering, to which a dial was attached for adjusting the speed of the motor.

**LIBELED:** 10-8-58, N. Dist. Tex.

**CHARGE:** 502(a)—the labeling accompanying the article, when shipped, contained false and misleading representations that the article was an adequate and effective treatment for relieving stiffness and soreness; reducing excess weight; improving elimination, weak instep, sore feet, and impaired circulation; breaking up congestion; stimulating kidneys and the nerves running to the intestines; overcoming congestion in the lower lungs; improving the digestion; overcoming liver sluggishness; overcoming congestion of the bronchial tubes and lung trouble; providing a deep kneading action for relieving congestion and sluggishness; helping to wake up dormant, congested organs in the abdomen; "doing away with unwanted bulges and fatty accumulations"; causing "pounds . . . to disappear"; and overcoming nervous tension.

**DISPOSITION:** 11-7-58. Consent—claimed by Edwin P. Farr and Joseph E. Farr, Dallas, Tex., and relabeled.

**5813. Renhill Cyclon Massager.** (F.D.C. No. 42247. S. No. 35-150 P.)

**QUANTITY:** 12 unlabeled devices and 6 labeled devices at Philadelphia, Pa.

**SHIPPED:** Between 7-3-58 and 8-25-58, from Newark, N.J., by Renhill Products Co.

**LABEL IN PART:** "Renhill Cyclon Massager."

**ACCOMPANYING LABELING:** Leaflet entitled "Here's New Body Beauty and Better Health" and card entitled "Slender-Health Massager."

**RESULTS OF INVESTIGATION:** The devices were an electromagnetic type vibrator mounted between two aluminum plates. The plates and vibrator were enclosed by polyurethane foam and a terry cloth cover.

**LIBELED:** 10-28-58, E. Dist. Pa.

**CHARGE:** 502(a)—the labeling accompanying the article, when shipped, contained false and misleading representations that the article was an adequate and effective treatment for stimulating blood circulation; relaxing nervous tension; increasing body nutrition; improving general metabolism; relieving constipation; reducing the figure; decreasing fatigue; relieving aches and pains from arthritis, rheumatism, lumbago, fibrositis, and bursitis; breaking down excess fatty tissues; aiding nature's own method of overcoming or relieving diseased conditions; providing passive exercise; and promoting and maintaining a general feeling of well-being.

**DISPOSITION:** 11-10-58. Default—destruction.

**5814. Vibratone device.** (F.D.C. No. 42214. S. No. 28-934 P.)

**QUANTITY:** 19 cartoned devices at New Orleans, La.

**SHIPPED:** Between 8-19-58 and 9-23-58, from Dallas, Tex., by the Walton Mfg. Co.

**ACCOMPANYING LABELING:** Booklet entitled "Line Design Vibratone," advertising formats, and a newspaper advertisement tear sheet.

**RESULTS OF INVESTIGATION:** The newspaper tear sheet and the advertising formats were furnished by the shipper, and a copy of the booklet was enclosed in each carton containing a device.

The device consisted of a stand or base into which a long metal tube with an electric motor on top was mounted. A long web belt attached to each end of the motor vibrated when the motor was switched on. The motor was enclosed in a protective and decorative covering, to which a dial was attached for adjusting the speed of the motor.

**LIBELED:** 10-3-58, E. Dist. La.

**CHARGE:** 502(a)—when shipped and while held for sale, the accompanying labeling of the device contained false and misleading representations that the device was an adequate and effective treatment for aiding in "spot reducing by breaking down fatty tissues directly under the skin," firming loose skin, and keeping muscles and skin firm and healthy; increasing and improving circulation of blood; breaking up congestion; improving elimination; overcoming common backache; stimulating kidneys and nerves running to intestines; easing built up tensions; and was capable and adequate to "redesign your lines."

**DISPOSITION:** 11-15-58. Consent—claimed by Walton Mfg. Co. and relabeled.

**5815. Leisure Cushion devices.** (F.D.C. No. 42012. S. No. 41-953 P.)

**QUANTITY:** 254 devices at Seattle, Wash.

**SHIPPED:** Between 3-12-58 and 5-12-58, from Centralia, Ill., by Centralia Beauty Supply.

**ACCOMPANYING LABELING:** Leaflets entitled "Now It's Here! Leisure Cushion."

**RESULTS OF INVESTIGATION:** The devices consisted of rigid-frame upholstered cushions, covered with a plastic material, and enclosing an on-off controlled electric motor capable of providing vibration.

**LIBELED:** 9-3-58, W. Dist. Wash.

**CHARGE:** 502(a)—the labeling accompanying the devices, when shipped, contained false and misleading representations that the devices were an adequate and effective treatment for increasing blood circulation, breaking down fatty tissue, reducing "unwanted bulges on hips, thighs, arms, stomach, and waist-line, acting as a 'spot' reducer," and that they were capable of aiding one to retain a firmer, more graceful figure; and 502(b)(1)—the devices failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor.

**DISPOSITION:** 12-4-58. Consent—claimed by Vin Co., Inc., Centralia, Ill., and relabeled.

**5816. Easytrim Cushion Vibrator.** (F.D.C. No. 42249. S. No. 31-319 P.)

**QUANTITY:** 32 devices at Bronx, N.Y.

**SHIPPED:** 6-4-58, from Newark, N.J., by the Easytrim Mfg. Co.

**LABEL IN PART:** (Metal tag on device) "Easytrim Cushion Vibrator."

**ACCOMPANYING LABELING:** Leaflet entitled "Reduce While Relaxing \* \* \* Easytrim Cushion Vibrator."

**RESULTS OF INVESTIGATION:** Examination showed that the device was a rectangular cushion with a built-in electrically operated vibrator mechanism.

**LIBELED:** 10-31-58, S. Dist. N.Y.

**CHARGE:** 502(a)—the labeling of the device, when shipped, contained false and misleading representations that the device was an adequate and effective treatment for causing one to lose weight, producing "spot reduction" of any selected area of the body, and providing a deep penetrating action.

**DISPOSITION:** 12-1-58. Default—destruction.



**5817. Eska Slimline device.** (F.D.C. No. 42291. S. No. 28-836 P.)

**QUANTITY:** 22 individually cartoned devices at New Orleans, La.

**SHIPPED:** 7-29-58 and 10-29-58, from Dubuque, Iowa, by Eska Co., Inc.

**LABEL IN PART:** (Device and ctn.) "Slimline Eska Company Dubuque, Iowa."

**ACCOMPANYING LABELING:** Leaflet in carton entitled "How To Use Your Eska Slimline."

**RESULTS OF INVESTIGATION:** The article consisted of a stand or base into which a long metal tube was mounted with an electric motor on top. A long canvas belt was attached to each end of the motor and when the motor was switched on the belt vibrated. Attached to the motor housing was a dial for adjusting the speed of the motor.

**LIBELED:** 11-12-58, E. Dist. La.

**CHARGE:** 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for stimulating the kidneys and nerves running to the intestines; increasing and improving blood circulation, and helping to break up congestion; overcoming common backache; easing sore muscles and joints; improving general skin tone; reducing the size of the hips and removing excess fat from the back, abdomen, thighs, and other parts of the body; and that it could be effectively used to "take off inches where they aren't wanted and put them on where they're needed" so as to "redesign your figure."

**DISPOSITION:** 12-19-58. Consent—claimed by Eska Co., Inc., and relabeled.

**5818. Electric massage pillow.** (F.D.C. No. 41961. S. No. 31-556 P.)

**QUANTITY:** 70 devices at Newark, N.J.

**SHIPPED:** 3-21-58, from New York, N.Y., by Leonard M. Schur, Inc.

**ACCOMPANYING LABELING:** A leaflet entitled "Leonard's Contour Design Electric Massage Pillow."

**LIBELED:** 7-31-58, Dist. N.J.

**CHARGE:** 502(a)—the labeling accompanying the article, when shipped, contained false and misleading representations that the device was an adequate and effective treatment for easing tensions, aching backs due to muscular strain, reducing thighs, firming abdominal muscles, and trimming surplus fatty tissue from hips.

**DISPOSITION:** 10-22-58. Consent—claimed by Leonard M. Schur, Inc., and relabeled.

**5819. Trim-Form table.** (F.D.C. No. 42187. S. No. 4-829 P.)

**QUANTITY:** 31 devices at Washington, D.C.

**SHIPPED:** Between 3-26-58 and 7-23-58, from North Hollywood, Calif., by Wizard Mfg. Co.

**LABEL IN PART:** (Metal plate on device) "Trim-Form by Wizard North Hollywood, Calif."

**ACCOMPANYING LABELING:** Folders entitled "Now For A More Youthful You," cards entitled "Trim-Form Progress Record," and leaflets entitled "Figure Consultant's Home Presentation."

**RESULTS OF INVESTIGATION:** The article was a box-like device enclosing a vibrating motor and fitted on the top with an upholstered cushion through which the vibrations were transmitted. Two removable extensions attach to either end of the motor section to comprise the *Trim-Form table*.

**LIBELED:** 9-15-58, Dist. Columbia.

**CHARGE:** 502(a)—the labeling of the article, when shipped and while held for sale, contained false and misleading representations that the article was an adequate and effective treatment for correcting posture, weight reduction, conditions associated with menopause, arthritis, bursitis, rheumatism, diabetes, high and low blood pressure, varicose veins, and circulatory disorders; correcting bone alignment, increasing circulation and elimination, toning muscles, reactivating the glands, changing the blood chemistry, and raising the metabolism.

**DISPOSITION:** 1-7-59. Consent—claimed by Trim-Form Corp., of Washington, D.C., and relabeled.

### DRUG ACTIONABLE BECAUSE OF FAILURE TO COMPLY WITH PACKAGING REQUIREMENTS OF AN OFFICIAL COMPENDIUM

**5820. Ascorbic acid injection.** (F.D.C. No. 41875. S. No. 26-345 P.)

**QUANTITY:** 110 ampuls at Minneapolis, Minn.

**SHIPPED:** 2-3-58, from Philadelphia, Pa., by Philadelphia Ampoule Laboratories.

**LABEL IN PART:** (Ampul) "1 cc \* \* \* Intramuscular Ascorbic Acid 100 mg Philadelphia Ampoule Laboratories \* \* \* 90019" and "1 cc \* \* \* Sodium Ascorbate Injection 500 mg. \* \* \* Phila. Amp. Labs., Phila. 23, Pa. 80186 [or "80392"]."

**RESULTS OF INVESTIGATION:** Examination showed that part of the solution had leaked through minute holes at the "sealed" end of some of the ampuls resulting in contamination of the remaining contents by air, and in loss of contents from such ampuls; and, that the remaining liquid content of the leading ampuls was discolored, presumably as a result of oxidation by the air which had entered the ampuls.

**LIBELED:** 6-23-58, Dist. Minn.

**CHARGE:** 502(g)—the article purported to be a drug, ascorbic acid injection, the name of which is recognized in the United States Pharmacopeia, and official compendium, and when shipped and while held for sale, the article was not packaged as prescribed in such compendium.

**DISPOSITION:** 8-12-58. Default—destruction.

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## SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

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digitalis powder, digitalis tablets, and digitalis capsules..	5787	Super Nucleol capsules.....	5802

<sup>1</sup> (5808) Prosecution contested. Contains opinion of the court.<sup>2</sup> (5781) Contempt of injunction. Contains supplemental consent decree.



	N.J. No.		N.J. No.
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and Pollen Gold Food Sup-			
plement-----	5805		

<sup>1</sup> (5808) Prosecution contested. Contains opinion of the court.<sup>2</sup> (5781) Contempt of injunction. Contains supplemental consent decree.

	N.J. No.		N.J. No.
Page Drugs:		Stegman, H. A.:	
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Philadelphia Ampoule Labora-		nal cancer-----	<sup>2</sup> 5781
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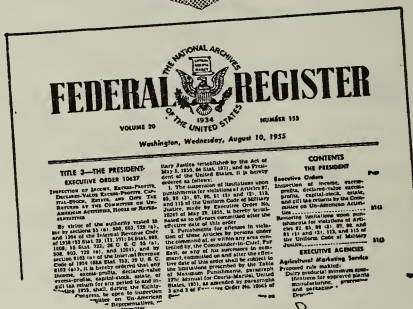
<sup>2</sup> (5781) Contempt of injunction. Contains supplemental consent decree.

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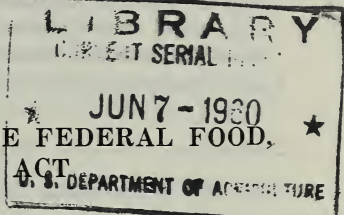


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# U.S. Department of Health, Education, and Welfare

## FOOD AND DRUG ADMINISTRATION



### NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

5821-5860

## DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs which are required at time of interstate shipment to bear a label containing the statement "Caution: Federal law prohibits dispensing without prescription," and which were dispensed after such shipment without a prescription or by refilling a prescription without authorization. This dispensing was contrary to Section 503(b)(1) and thereby resulted in the dispensed drugs being misbranded while held for sale.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., April 29, 1960.

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## VIOLATIVE SALES OF PRESCRIPTION DRUGS

5821. (F.D.C. No. 43248. S. Nos. 27-460 P, 51-966/7 P, 51-981 P.)

INFORMATION FILED: 10-29-59, N. Dist. Iowa, against **Harold Kramer, t/a Kramer Truck Stop and Cafe and Kramer Mobil Service and Cafe, Blairsburg, Iowa, and Willie Herman Rose, an employee.**

CHARGE: Between 3-10-59 and 4-10-59, *amphetamine sulfate tablets* (counts 1, 2, and 3) were dispensed 3 times, and *dextro-amphetamine sulfate capsules* (count 4) were dispensed once without a prescription.

PLEA: Guilty by Kramer to all counts of information and by Rose to counts 1 and 4.

DISPOSITION: 11-4-59. Kramer fined \$200 and Rose \$50.

5822. (F.D.C. No. 43066. S. Nos. 16-460 P, 16-820 P, 17-470/1 P, 17-474/5 P, 17-477/8 P.)

INFORMATION FILED: 5-19-59, N. Dist. Ohio, against **Raymond Krempa, t/a Oak Pharmacy, Toledo, Ohio, and Raymond C. Krall (pharmacist).**

CHARGE: Between 8-27-58 and 10-3-58, *amphetamine sulfate tablets* were dispensed 8 times without a prescription.

PLEA: Nolo contendere by Krempa to all counts of the information and by Krall to 4 counts.

DISPOSITION: 6-19-59. Krempa—\$1,600 fine and Krall—\$200 fine.

5823. (F.D.C. No. 42405. S. Nos. 25-314/7 P, 25-319 P.)

INFORMATION FILED: 12-22-58, Dist. Minn., against **Morton B. Gross (pharmacist and operator of Oak Knoll Drug), Minneapolis, Minn.**

CHARGE: Between 2-5-58 and 2-10-58, *amphetamine sulfate tablets* and *Butisol Sodium tablets* were each dispensed twice and *Amytal tablets* were dispensed once upon requests for prescription refills without authorization by a prescriber.

PLEA: Guilty.

DISPOSITION: 3-9-59. \$1,250 fine and probation for 5 years.

5824. (F.D.C. No. 41767. S. Nos. 1-165 P, 1-167 P, 2-381 P, 2-405 P.)

INFORMATION FILED: 10-14-58, S. Dist. Fla., against **Salvatore P. Leone, t/a White Cross Pharmacy, Miami, Fla.**

CHARGE: Between 1-31-58 and 2-24-58, *dextro-amphetamine sulfate tablets* were dispensed 4 times without a prescription.

DISPOSITION: On 11-7-58, the defendant filed a motion to dismiss. The court, after a hearing, overruled the motion on 1-23-59. On 1-30-59, the defendant entered a plea of nolo contendere and was fined \$600 and placed on probation for 1 year.

5825. (F.D.C. No. 42450. S. Nos. 1-226 P, 1-228 P, 2-755 P, 44-381 P, 44-383 P, 44-389 P, 44-391 P.)

INFORMATION FILED: About 3-26-59, N. Dist. Ga., against **Benjamin W. Medlock, t/a Medlock Drug Co., Atlanta, Ga., and Frank R. Cooley (pharmacist).**

CHARGE: Between 8-29-58 and 10-14-58, *dextro-amphetamine sulfate tablets* were dispensed 7 times upon requests for a prescription refill without authorization from the prescriber.

PLEA: Nolo contendere by Medlock to all counts of the information and by Cooley to counts 1, 4, and 6.

DISPOSITION: 7-22-59. Medlock—\$400 fine and probation for 2 years; Cooley—\$150 fine and probation for 2 years.

5826. (F.D.C. No. 42420. S. Nos. 13-191/2 P, 13-195/6 P, 13-198/9 P.)

INFORMATION FILED: 1-22-59, N. Dist. Ind., against Harry P. Ochstein, t/a Avenue Pharmacy, Hammond, Ind.

CHARGE: Between 2-8-58 and 4-11-58, *dextro-amphetamine sulfate capsules* and *methyltestosterone tablets* were each dispensed twice and *Dexamobarb capsules* and *secobarbital sodium capsules* were each dispensed once without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 8-10-59. The defendant was fined \$300, plus costs, given a prison sentence of 1 year, which was suspended, and placed on probation for 3 years.

5827. (F.D.C. No. 42414. S. Nos. 31-283/4 P, 31-687 P, 31-694 P.)

INFORMATION FILED: 2-16-59, S. Dist. N.Y., against Martin A. Wolfson, t/a Perry Hill Pharmacy, Bronx, N.Y.

CHARGE: Between 6-10-58 and 7-10-58, *dextro-amphetamine sulfate tablets* (counts 1 and 4) were dispensed twice upon request for prescription refills without authorization from the prescriber, and *AM Plus capsules* (count 2) and *Metandren Linguets* (count 3) were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 8-19-59. \$600 fine.

5828. (F.D.C. No. 43048. S. Nos. 21-545/6 P.)

INFORMATION FILED: 4-8-59, W. Dist. Mo., against Edgar J. Goin, t/a E. J. Goin Drug Store, Kansas City, Mo., and Lois F. Davis (pharmacist).

CHARGE: Between 11-7-58 and 11-13-58, *tablets containing a mixture of amobarbital and dextro-amphetamine sulfate* (count 1) and *meprobamate tablets* (count 2) were each dispensed once without a prescription.

PLEA: Nolo contendere by Goin to both counts of the information and by Davis to count 2.

DISPOSITION: 5-1-59. Davis—probation for 2 years; Goin—fine of \$1,000, plus costs.

5829. (F.D.C. No. 42408. S. Nos. 16-689/92 P, 16-694 P.)

INFORMATION FILED: 1-30-59, E. Dist. Tenn., against Sharp's Drug Store No. 3, Inc., Knoxville, Tenn., and Thomas O. Day, Jr., (president).

CHARGE: Between 4-16-58 and 7-9-58, *Benzedrine Sulfate tablets* (counts 1 and 4) were dispensed twice, and *Equanil tablets* (count 2), *Benzedrine Sulfate Spansule capsules* (count 3), and *Seconal Sodium capsules* (count 5) were each dispensed once without a prescription.

PLEA: Nolo contendere by defendant Day; guilty by the corporation.

DISPOSITION: 6-4-59, Day—\$500 fine; 8-14-59, corporation—\$400 fine on each of counts 1 to 4 inclusive and imposition of sentence reserved on count 5.



5830. (F.D.C. No. 43238. S. Nos. 1-248 P, 56-298 P, 56-324 P, 56-331 P, 56-335 P, 56-490 P.)

INFORMATION FILED: 9-23-59, S. Dist. Ga., against **Joe Martin, t/a Martin's Pharmacy, Uvalda, Ga.**

CHARGE: Between 1-12-59 and 3-30-59, *Benzedrine Sulfate tablets* were dispensed 6 times without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 11-10-59. \$300 fine and probation for 2 years.

5831. (F.D.C. No. 43050. S. Nos. 6-427 P, 7-434 P, 7-436/8 P, 7-554/6 P, 7-764/7 P.)

INFORMATION FILED: 4-30-59, Dist. Mass., against **Lawrence J. Murphy, t/a L. J. Murphy, Woburn, Mass., Charles Argetes and Paul Cogan (pharmacists), and Frank Power (clerk).**

CHARGE: Between 5-16-58 and 7-16-58, *Dexedrine Sulfate tablets* were dispensed 9 times and *Nembutal capsules* were dispensed 3 times upon requests for prescription refills without authorization from a prescriber.

PLEA: Guilty by Murphy to all 12 counts of the information; by Power to 4 counts; by Cogan to 3 counts; and by Argetes to 2 counts.

DISPOSITION: 6-29-59. Murphy—\$1,000 fine and probation for 2 years; Argetes and Cogan—\$200 fine each and probation for 2 years; Power—\$100 fine and probation for 2 years.

5832. (F.D.C. No. 43057. S. Nos. 41-427/9 P, 41-431/3 P, 41-435/7 P.)

INFORMATION FILED: 4-14-59, Dist. Idaho, against **Clifford H. Harper, t/a Serv-A-Center Drug, Nampa, Idaho, and Paul E. Stockard (pharmacist).**

CHARGE: Between 5-17-58 and 6-11-58, *Sulfedexan solution* was dispensed 3 times (counts 1, 2, and 3), *penicillin G potassium tablets* were dispensed twice (counts 4 and 5), and *dextro-amphetamine sulfate tablets* were dispensed 4 times (counts 6, 7, 8, and 9) without a prescription.

PLEA: Nolo contendere by Harper to counts 1, 2, 5, and 7 and by Stockard to counts 3, 4, 6, 8, and 9.

DISPOSITION: 5-11-59. \$80 fine each.

5833. (F.D.C. No. 42464. S. Nos. 21-663/4 P.)

INFORMATION FILED: 4-7-59, Dist. Nebr., against **Robert J. Rebal (pharmacist), Omaha, Nebr.**

CHARGE: Between 9-24-58 and 9-29-58, *pentobarbital sodium capsules* were dispensed twice without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 5-7-59. \$200 fine, plus costs.

5834. (F.D.C. No. 42468. S. Nos. 28-263/8 P.)

INFORMATION FILED: 5-21-59, N. Dist. Ala., against **Cloverdale Drug Co. (a partnership), Bessemer, Ala., and Roy E. Phipps and Jack Brasher (pharmacists).**

CHARGE: Between 4-26-58 and 5-1-58, *pentobarbital sodium capsules* (counts 2, 4, and 5) were dispensed 3 times, *Miltown tablets* (counts 1 and 3) twice, and *Equanil tablets* (count 6) once upon requests for prescription refills without authorization from a prescriber.

PLEA: Guilty by the partnership to all counts; by Phipps to counts 2, 3, and 4; and by Brasher to counts 5 and 6.

DISPOSITION: 6-10-59. Partnership—\$100 fine; individuals—\$200 fine each.

5835. (F.D.C. No. 43097. S. Nos. 21-238/40 P, 21-617 P, 22-163 P.)

INFORMATION FILED: 6-16-59, W. Dist. Mo., against **George A. MacKay, t/a MacKay Drug, Kansas City, Mo.**

CHARGE: Between 1-9-59 and 1-26-59, *pentobarbital sodium capsules* were dispensed twice and *Chloromycetin capsules* were dispensed once upon requests for refills of prescriptions without authorization from a prescriber, and *Terramycin Hydrochloride capsules* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 6-19-59. \$500 fine, plus costs.

5836. (F.D.C. No. 43108. S. Nos. 19-838 P, 19-842 P, 19-845 P, 19-852/5 P.)

INFORMATION FILED: 7-1-59, W. Dist. Okla., against **Fern S. Wythe, t/a Wythe Drug Store No. 1, Oklahoma City, Okla.**

CHARGE: Between 1-20-59 and 2-11-59, *pentobarbital sodium capsules* were dispensed 5 times upon requests for refills of a prescription without authorization by the prescriber, and *Sulfose Suspension* was dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 8-21-59. Defendant was placed on probation for 5 years.

5837. (F.D.C. No. 42458. S. Nos. 18-705 P, 18-716 P, 18-719 P, 18-724 P, 18-737 P, 18-758 P.)

INFORMATION FILED: 1-27-59, against **Paul W. Brown, t/a Del Norte Pharmaceuticals, El Paso, Tex.**

CHARGE: Between 2-6-58 and 4-19-58, *secobarbital sodium capsules* were dispensed 5 times and *dextro-amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 3-6-59. Suspended sentence of 1 year in jail and probation for 1 year.

5838. (F.D.C. No. 43053. S. Nos. 21-572 P, 21-645 P, 21-648/9 P, 21-659/60 P.)

INFORMATION FILED: 4-15-59, E. Dist. Okla., against **John M. Walker, t/a Walker's Drug Store, Haskell, Okla.**

CHARGE: Between 9-29-58 and 10-23-58, *Seconal Sodium capsules* were dispensed 4 times and *Synatan tablets* were dispensed once upon requests for prescription refills without authorization from a prescriber, and *meprobrate tablets* were dispensed once without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 4-23-59. \$110 fine.

5839. (F.D.C. No. 42447. S. Nos. 9-411/2 P, 9-681/4 P, 10-022/4 P, 10-030/1 P.)

INFORMATION FILED: 6-12-59, W. Dist. N.Y., against **James L. Battaglia, t/a North Main Pharmacy, Jamestown, N.Y., and Frances M. Barker (pharmacist).**

CHARGE: Between 7-17-58 and 8-27-58, *Seconal Sodium capsules* (counts 1, 2, 3, and 7) were dispensed 4 times, *Compazine Spansule capsules* (counts 4, 8, and 11) were dispensed 3 times, and *Dexedrine Sulfate tablets* (counts 6 and 10) were dispensed twice upon requests for prescription refills without authorization from a prescriber, and *AM Plus capsules* (counts 5 and 9) were dispensed twice without a prescription.

PLEA: Nolo contendere by Battaglia to all counts and by Barker to counts 1, 6, and 11.

DISPOSITION: 7-22-59. Battaglia—\$400 fine; Barker—\$50 fine.

5840. (F.D.C. No. 42438. S. Nos. 8-268 P, 8-290 P, 8-746 P.)

INFORMATION FILED: 4-1-59, N. Dist. N.Y., against **Benjamin Berke, t/a Berke's Drug Store, Rome, N.Y., Dominick Capponi (clerk), and Edwin L. Comins (pharmacist).**

CHARGE: Between 3-3-58 and 3-15-58, *Seconal Sodium capsules* (counts 1 and 2) were dispensed twice and *Dexedrine Spansule capsules* (count 3) were dispensed once upon requests for prescription refills without authorization from a prescriber.

PLEA: Guilty by Berke to counts 1 and 2; by Comins to count 2; and by Capponi to count 3.

DISPOSITION: 7-13-59. Berke—\$700 fine; Comins and Capponi—each \$200 fine.

5841. (F.D.C. No. 41172. S. Nos. 76-918 M, 76-923 M, 76-926 M, 76-931 M, 77-206 M, 77-208 M.)

INFORMATION FILED: 5-17-58, N. Dist. Ga., against **Bradford Drug Co., Inc., Cedartown, Ga., Henry Tare Bradford (president and treasurer of the corporation), and Edwin Gibson Ivey (an employee of the corporation).**

CHARGE: Between 7-11-57 and 8-5-57, *Seconal Sodium capsules* were dispensed 6 times upon requests for prescription refills without authorization by the prescriber.

DISPOSITION: The defendants having entered a plea of not guilty, the case came on for trial before the court and jury on 3-20-59. The trial was concluded on 3-24-59, with the court declaring a mistrial because of the failure of the jury to reach a verdict.

On 11-4-59, pleas of nolo contendere were entered by the corporation to all 6 counts of the information; by Henry Bradford to counts 1, 2, and 5; and by Edwin Ivey to counts 3, 4, and 6. On the same day, the court fined the corporation \$125, Henry Bradford \$250, and Edwin Ivey \$75. The court also placed each individual on probation for 1 year.

5842. (F.D.C. No. 42446. S. Nos. 75-653 M, 22-930/1 P, 22-933 P, 22-952 P.)

INFORMATION FILED: 5-15-59, Dist. Ariz., against **Herbert C. Brightbill and Herman M. Hoffman (pharmacists), Tucson, Ariz.**

CHARGE: Between 12-19-57 and 2-25-58, *Seconal Sodium capsules* and *Thorazine tablets* were each dispensed twice and *Meticorten tablets* were dispensed once upon request for prescription refills without authorization from the prescriber.



PLEA: Guilty by Brightbill to 3 counts involving the dispensing of *Seconal Sodium capsules*, *Thorazine tablets*, and *Meticorten tablets*; and by Hoffman to 2 counts involving the dispensing of *Seconal Sodium capsules* and *Thorazine tablets*.

DISPOSITION: 10-12-59. Both defendants were placed on probation for 1 year.

5843. (F.D.C. No. 43696. S. Nos. 50-881/4 P.)

INFORMATION FILED: 11-29-59, N. Dist. Ind., against Leroy Wineinger (pharmacist), t/a DeKalb Drugs, East Gary, Ind.

CHARGE: Between 1-14-59 and 3-3-59, *Miltown tablets* and *Dexedrine Spansule capsules* were each dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 12-4-59. \$200 fine, plus costs.

5844. (F.D.C. No. 42413. S. Nos. 11-985/6 P.)

INFORMATION FILED: 1-7-59, N. Dist. Ind., against Morris B. F. Victor (pharmacist), East Chicago, Ind.

CHARGE: On 4-17-58, *Gantrisin tablets* and *dextro-amphetamine sulfate capsules* were each dispensed once without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 1-14-59. \$150 fine, plus costs.

5845. (F.D.C. No. 41728. S. Nos. 61-157 M, 75-979 M, 76-015 M, 76-042 M, 76-104 M, 76-161 M.)

INFORMATION FILED: 12-16-58, Dist. Mass., against Hemenway Drug Co. (a corporation), Boston, Mass., Nicholas T. Elias (pharmacist), and Charles Bowen (employee).

CHARGE: Between 6-18-57 and 7-25-57, *Gantrisin tablets* (counts 1 and 5), *Butazolidin tablets* (counts 2 and 6), and *Thorazine tablets* (counts 3 and 4), were each dispensed twice upon request for prescription refills without authorization by a prescriber.

PLEA: Nolo contendere by the corporation to all counts; by Elias to counts 1, 2, and 3; and by Bowen to counts 4, 5, and 6.

DISPOSITION: 10-13-59. Corporation—\$300 fine; Elias—\$200 fine; Bowen—\$100 fine.

5846. (F.D.C. No. 41164. S. Nos. 57-225 M, 57-245 M.)

INFORMATION FILED: 3-12-58, S. Dist. Fla., against Harry N. Chastain and Hugh H. Lumpkin (pharmacists), West Palm Beach, Fla.

CHARGE: Between 7-30-57 and 8-24-57, *Azo Gantrisin tablets* were dispensed twice upon requests for prescription refills without authorization by the prescriber.

PLEA: Nolo contendere.

DISPOSITION: 3-21-58. Each defendant placed on probation for 1 year.

5847. (F.D.C. No. 42163. S. Nos. 81-930/2 M, 81-941/2 M, 81-946 M, 28-181/2 P, 28-184 P.)

INFORMATION FILED: 3-24-59, N. Dist. Tex., against Isaac M. Neal, t/a Smith Drug Store, and also as Neal Drug, Cross Plains, Tex.

CHARGE: Between 8-7-57 and 2-11-58, *Erythromid tablets* were dispensed 5 times, *Dewedrine Sulfate tablets* 3 times, and *thyroid tablets* once, without a prescription.

PLEA: Not guilty.

DISPOSITION: The case came on for trial before a jury on 11-12-59. On 11-13-59, the jury found the defendant not guilty on 8 counts and guilty on 1 count involving the dispensing of *thyroid tablets*. On 11-13-59, the defendant was fined \$1,000 and sentenced to 90 days in jail.

5848. (F.D.C. No. 42421. S. Nos. 1-013 P, 1-020/1 P, 1-027/30 P, 1-034/5 P, 2-775 P.)

INFORMATION FILED: 3-3-59, N. Dist. Ga., against Robert Jordan Bradley, t/a Woodbine Pharmacy, Atlanta, Ga., and Billy Leroy Lowry (pharmacist).

CHARGE: Between 4-30-58 and 7-1-58, *meprobamate tablets* (counts 1, 2, 5, 6, and 8) were dispensed 5 times, *pentobarbital sodium capsules* (counts 3, 4, 7, and 9) were dispensed 4 times, and *Dewedrine Sulfate tablets* (count 10) were dispensed once, upon requests for prescription refills without authorization by the prescriber.

PLEA: Nolo contendere by Bradley to all counts of the information and by Lowry to counts 1, 6, 7, and 10.

DISPOSITION: 4-2-59. Bradley—\$750 fine and probation for 2 years; Lowry—\$100 fine and probation for 2 years.

5849. (F.D.C. No. 41155. S. Nos. 57-226 M, 57-243 M.)

INFORMATION FILED: 3-12-58, S. Dist. Fla., against Jack R. Penberthy and William R. Plank (pharmacists), West Palm Beach, Fla.

CHARGE: Between 7-30-57 and 8-21-57, *Prednisone tablets* and *pentobarbital sodium capsules* were each dispensed once upon requests for prescription refills without authorization by the prescriber.

PLEA: Nolo contendere.

DISPOSITION: 3-21-58. Each defendant placed on probation for 1 year.

5850. (F.D.C. No. 43051. S. Nos. 31-158 P, 31-267 P, 31-629 P, 31-804 P.)

INFORMATION FILED: 5-5-59, S. Dist. N.Y., against Max Rimer, t/a Majestic Pharmacy, Bronx, N.Y.

CHARGE: Between 8-13-58 and 8-26-58, *Bicillin tablets* and *AM Plus capsules* were each dispensed once without a prescription, and *Desowyn Hydrochloride tablets* and *Seconal Sodium capsules* were each dispensed once upon request for a prescription refill without authorization by the prescribers.

PLEA: Guilty.

DISPOSITION: 8-5-59. \$150 fine and probation for 1 day.

5851. (F.D.C. No. 42404. S. Nos. 6-535 P, 6-538/9 P, 6-544 P, 6-866 P, 6-870 P, 7-160 P, 7-165 P, 7-170 P, 7-178 P, 7-326/7 P.)

INFORMATION FILED: 4-30-59, Dist. Mass., against Brooks Pharmacy (a partnership), East Boston, Mass., Saul Davis and Albert E. Davis (partners), and Antonio Masci (pharmacist).

CHARGE: Between 2-3-58 and 3-26-58, *Banthine tablets*, *Thorazine tablets*, and *Gantrisin tablets*, were each dispensed 4 times upon requests for prescription refills without authorization from a prescriber.

PLEA: Guilty by the partnership to all counts of the information; by Saul Davis to 7 counts; by Antonio Masci to 3 counts; and by Albert Davis to 2 counts.

DISPOSITION: 6-26-59. Partnership—\$500 fine; Saul Davis—\$250 fine and probation for 1 year; Antonio Masci—\$100 fine and probation for 1 year; Albert E. Davis—probation for 1 year.

5852. (F.D.C. No. 42390. S. Nos. 2-512/3 P, 2-516/7 P, 2-529 P.)

INFORMATION FILED: 12-16-58, S. Dist. Fla., against Robert D. Sistrunk, Jr., t/a Cash Drug Co., Dade City, Fla.

CHARGE: Between 4-11-58 and 5-23-58, *Nembutal capsules* were dispensed twice, and *penicillin V potassium tablets* were dispensed once without a prescription, and *Dexedrine Sulfate tablets* were dispensed twice upon requests for prescription refills without authorization by the prescriber.

PLEA: Guilty.

DISPOSITION: 4-17-59. \$250 fine and probation for 5 years.

5853. (F.D.C. No. 40429. S. Nos. 67-515/7 M, 67-526 M.)

INDICTMENT RETURNED: 12-2-57, E. Dist. Va., against Morris H. Yarmack (a pharmacist for the Falls Church Drug Store), Falls Church, Va.

CHARGE: Between 4-10-57 and 4-18-57, *penicillin G potassium tablets* were dispensed 3 times and *Dexedrine Sulfate tablets* were dispensed once without a prescription.

PLEA: Not guilty.

DISPOSITION: The case came on for trial before the court and jury on 6-6-58. The jury returned a verdict of guilty on 6-9-58, and, on 6-18-58, the court imposed a sentence of 7 months in jail against the defendant.

5854. (F.D.C. No. 42411. S. No. 11-801 P.)

INFORMATION FILED: 3-16-59, E. Dist. Mich., against Otto Racette (a pharmacist), Auburn Heights, Mich.

CHARGE: On 2-22-58, *Metadren Linguets* were dispensed once without a prescription.

PLEA: Not guilty.

DISPOSITION: 8-19-59. After a trial before the court without a jury, the defendant was found not guilty.

5855. (F.D.C. No. 43095. S. Nos. 32-032 P, 32-285 P.)

INFORMATION FILED: 7-15-59, E. Dist. N.Y., against Martin Harnick, t/a Martin Drugs, Ridgewood, N.Y.

CHARGE: Between 10-2-58 and 10-6-58, *Doriden tablets* and *Desoxyn Hydrochloride tablets* were each dispensed once upon requests for prescription refills without authorization by the prescribers.

PLEA: Guilty.

DISPOSITION: 10-9-59. \$1,000 fine.

5856. (F.D.C. No. 43109. S. Nos. 32-037 P, 32-294 P.)

INFORMATION FILED: 8-12-59, E. Dist. N.Y., against Friendly Drug Stores, Inc., Ridgewood, N. Y., and Max Allahut (president and pharmacist).



CHARGE: Between 9-23-58 and 10-6-58, *Desoxyn Hydrochloride tablets* and *Doriden tablets* were each dispensed once upon requests for prescription refills without authorization by the prescriber.

PLEA: Guilty.

DISPOSITION: 10-9-59. Each defendant fined \$1,000.

5857. (F.D.C. No. 42454. S. Nos. 75-301/2 M, 75-309 M, 22-919 P, 22-921/2 P, 22-924 P.)

INFORMATION FILED: 5-15-59, Dist. Ariz., against Richard L. Gibson, t/a **Eureka Drugs, Tucson, Ariz., and Morris Rosenthal (pharmacist).**

CHARGE: Between 12-10-57 and 2-18-58, *Meticorten tablets*, *Dexedrine Spansule capsules*, and *amobarbital sodium capsules*, were each dispensed twice, and *Thorazine tablets* were dispensed once without a prescription.

PLEA: Guilty by Rosenthal to one of the counts involving the dispensing of *Meticorten tablets* and by Gibson to the remaining counts.

DISPOSITION: 6-15-59. Gibson—probation for 6 months; 10-12-59, Rosenthal—probation for 1 year.

5858. (F.D.C. No. 43064. S. Nos. 22-904 P, 22-907 P, 22-911 P.)

INFORMATION FILED: 5-15-59, Dist. Ariz., against T. Ed Litt Drug Co., Inc., Tucson, Ariz., and C. Aubrin Anderson and Roy Petersen (pharmacists).

CHARGE: Between 1-15-58 and 1-22-58, *Meticorten tablets*, *Proloid tablets*, and *amobarbital sodium capsules*, were each dispensed once upon request for prescription refills without authorization by the prescribers.

PLEA: Guilty by the corporation to all counts; by Anderson to the counts involving the dispensing of *Meticorten tablets* and *Proloid tablets*; and by Petersen to the count involving the dispensing of *amobarbital sodium capsules*.

DISPOSITION: 9-14-59. The corporation and the individuals were each placed on probation for 1 year.

5859. (F.D.C. No. 42463. S. Nos. 18-373 P, 18-377 P, 18-570 P.)

INFORMATION FILED: 5-27-59, Dist. Colo., against L. E. Hillman, D.O., Brush, Colo.

CHARGE: Between 2-5-58 and 3-4-58, *pentobarbital sodium capsules* were dispensed 3 times without a prescription.

PLEA: Guilty.

DISPOSITION: 10-30-59. \$300 fine.

5860. (F.D.C. No. 43224. S. Nos. 19-535/7 P, 42-982/3 P, 43-861 P, 43-863/5 P, 43-874 P.)

INFORMATION FILED: 8-12-59, Dist. Utah, against Berntsen & Evans Pharmacy, Inc., Provo, Utah, and Donald Holbrook (pharmacist).

CHARGE: Between 9-17-58 and 11-24-58, *tablets containing a mixture of carbromal and pentobarbital sodium* (counts 1 to 4 inclusive) were dispensed 4 times and *Chloromycetin capsules* (counts 5 and 6) and *Aristocort tablets* (counts 8 and 9) were each dispensed twice without a prescription; and *Dexedrine Spansule capsules* (count 7) and *Mictine tablets* (count 10) were each dispensed once upon requests for prescription refills without authorization by the prescriber.

PLEA: Guilty by the firm to all 10 counts of the information and by Holbrook to counts 1, 2, 5, 7, 8, 9, and 10.

DISPOSITION: 9-21-59. Firm—fines of \$500 on counts 1 and 2 and suspended fines of \$500 on each of the other counts; Holbrook—\$300 fine on count 1 and suspended fines of \$300 on each of counts 2, 5, 7, 8, 9, and 10.

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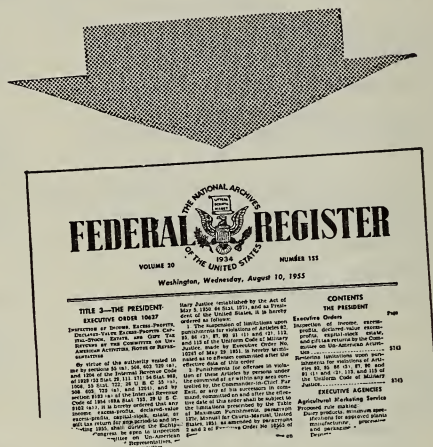


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## U.S. Department of Health, Education, and Welfare

## FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD,  
DRUG, AND COSMETIC ACTLIBRARY  
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[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

U. S. DEPARTMENT OF AGRICULTURE

5861-5900

## DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were adulterated or misbranded within the meaning of the Act when introduced into and while in interstate commerce or while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings in which decrees of condemnation were entered by default, or by consent, and including in one case the entry of a decree for injunction and (2) criminal proceedings terminated upon a plea of guilty or by a judgment of guilty after trial. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation, and the criminal proceedings are against the *firms* or *individuals* charged to be responsible for violations.

Published by direction of the Secretary of Health, Education, and Welfare.

GEORGE P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D.C., June 23, 1960.

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SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS  
REPORTED IN D.D.N.J. 5861-5900

*Adulteration*, Section 501(b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopoeia), and its strength differed from the standard set forth in such compendium; Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength differed from, or its purity or quality fell below, that which it purported or was represented to possess; and Section 501(d) (2), the article was a drug, and a substance had been substituted wholly or in part therefor.

*Misbranding*, Section 502(a), the labeling of the article was false and misleading; Section 502(b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; Section 502(e) (2), the article was a drug not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient including the quantity, kind, and proportion of alcohol contained therein; Section 502(f), the labeling of the article failed to bear (1) adequate directions for use; and (2) adequate warnings against use in those pathological conditions where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 502(j), the article was dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in its labeling; Section 502(l), three articles were, or purported to be, or were represented as, drugs composed partly of penicillin, and another article was represented as a drug composed partly of chlorotetracycline, and none of the articles were from a batch with respect to which a certificate or release had been issued pursuant to Section 507; and Section 503(b) (4), the article was a drug subject to Section 503(b) (1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

*New-drug violation*, Section 505(a), the article was a new drug within the meaning of Section 201(p), which was introduced into interstate commerce, and an application filed pursuant to Section 505(b) was not effective with respect to such drug.

DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED  
ACCORDING TO DIRECTIONS

DRUGS FOR HUMAN USE

5861. Private Formula tablets. (F.D.C. No. 42858. S. No. 6-059 P.)

QUANTITY: 51,000 tablets in bulk container at Washington, D.C.

SHIPPED: 1-22-59, from Philadelphia, Pa., by Hance Bros. & White Co.

LABEL IN PART: "Private Formula \* \* \* Each containing: d-1 Desoxyephedrine HCL 37½ mg. Phenobarbital ½ Gr. Warning \* \* \* Aloin ⅝ Gr. Dose: One tablet daily or as directed by physician. Hance Bros & White Co., \* \* \* Philadelphia."



**LIBELED:** 2-26-59, Dist. Columbia.

**CHARGE:** 502(j)—when shipped, the article was dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in its labeling.

**DISPOSITION:** 5-21-59. Default—destruction.

**5862. Barnes-Hind Wetting Solution.** (F.D.C. No. 43134. S. No. 62-351 P.)

**QUANTITY:** 21 doz., 2-oz. plastic btls. at Chicago, Ill.

**SHIPPED:** 2-19-59, from Sunnyvale, Calif., by Barnes-Hind Ophthalmic Products, Inc.

**LABEL IN PART:** (Plastic btl.) "Barnes-Hind Wetting Solution. An anti-septic wetting-out cleansing and sanitizing solution to be used with plastic contact lenses. \* \* \* Active Ingredients: Benzalkonium chloride 0.002% \* \* \* Barnes-Hind Ophthalmic Products, Inc., 895 Kifer Road, Sunnyvale, Calif."

**RESULTS OF INVESTIGATION:** Examination of the article showed that it was not sterile but was contaminated with viable micro-organisms of the *Pseudomonas* group.

**LIBELED:** 5-1-59, N. Dist. Ill.; amended 5-5-59.

**CHARGE:** 501(c)—when shipped, the purity or quality of the article fell below that which it purported or was represented to possess, since it was represented as suitable for use in the eye, whereas it was not suitable for such use by reason of contamination with *Pseudomonas*; and 502(j)—the article was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling, namely, "Directions: Gently rub 2 or 3 drops of Barnes-Hind Wetting Solution over the entire inner and outer surfaces of the lenses. Do not dry lenses before inserting."

**DISPOSITION:** 7-27-59. Default—destruction.

#### DRUG FOR VETERINARY USE

**5863. Crisp Tonic Pills (veterinary).** (F.D.C. No. 43170. S. No. 56-425 P.)

**QUANTITY:** 1 drum containing 4,500 tablets and 17 30-tablet boxes at Blacksburg, S.C., in possession of S. A. Crisp Canine Co.

**SHIPPED:** 8-30-47, from Passaic, N.J., by Purity Drug Co.

**LABEL IN PART:** (Drum) "Special Formula \* \* \* pills S. C. Brown Each Pill Contains: Strychnine Sulfate  $\frac{1}{120}$  gr. Arsenic Trioxide  $\frac{1}{60}$  gr. Reduced Iron 1 gr. Extract Gentian 1 gr. Caution \* \* \* Purity Drug Co. Inc., New York, N.Y. Passaic, N.J. 6603"; (box) "Crisp's Tonic Pills for Dogs \* \* \* Each Containing Reduced Iron 1 gr. Strychnine Sulphate  $\frac{1}{120}$  gr. Arsenic Trioxide  $\frac{1}{16}$  gr. Extract Gentian Q.S. Directions \* \* \* S. A. Crisp Canine Co., Blacksburg, S.C."

**ACCOMPANYING LABELING:** Pamphlets entitled "Crisp Canine Remedies."

**RESULTS OF INVESTIGATION:** The tablets in the boxes were shipped in bulk as described above and then were repacked and relabeled by the S. A. Crisp Canine Co. Analysis showed that the article contained about four times the declared amount of strychnine sulfate per tablet.

The pamphlets were prepared locally for the dealer.

**LIBELED:** 6-22-59, W. Dist. S.C.

CHARGE: 501(c)—the strength of the article, when shipped and while held for sale, differed from that which it purported to possess, namely, 1/120 grain strychnine sulfate per tablet; 502(a)—the label statements (drum and box) "Strychnine Sulphate 1/120 Gr." were false and misleading; 502(j)—the article was dangerous to health when used in the dosage, or with the frequency or duration recommended in the labeling; and 502(a)—the labeling of the repacked article, while held for sale, contained false and misleading representations and suggestions that the article was an adequate and effective treatment for overcoming "sluggish" symptoms in dogs and conditioning dogs after recovering from any disease; and the name "Tonic Pills" created the misleading impression that the article had unusual and general systemic conditioning and stimulating property.

DISPOSITION: 7-8-59. Consent—destruction.

#### NEW DRUG SHIPPED WITHOUT EFFECTIVE APPLICATION

5864. Antiseptic nasal spray. (F.D.C. No. 43159. S. No. 51-364 P.)

QUANTITY: 28,800 individually cartoned 15-cc btl. at Chicago, Ill.

SHIPPED: 8-13-57 and 8-19-57, from Cleveland, Ohio, by Strong, Cobb & Co., Inc.

LABEL IN PART: (Btl.) "F & F Antiseptic Nasal Spray \* \* \* Ingredients: Phenylephrine Hydrochloride 0.25% Pyrilamine Maleate 1.0% Tyrothricin 0.01% Cetyl Dimethyl Benzyl Ammonium Chloride 1:10,000 F & F Laboratories, Inc., Chicago 32, Illinois."

RESULTS OF INVESTIGATION: Analysis showed that the article contained 1 percent pyrilamine maleate as stated on the label.

LIBELED: 5-25-59, N. Dist. Ill.

CHARGE: 502(a)—when shipped and while held for sale, the labels of the article contained false and misleading representations that it was an adequate and effective treatment for sinusitis; and 505(a)—the article was a new drug which may not be introduced into interstate commerce since an application filed pursuant to law was not effective with respect to the drug.

DISPOSITION: 6-22-59. Default—destruction.

#### DRUG REQUIRING CERTIFICATE OR RELEASE, FOR WHICH NONE HAD BEEN ISSUED

5865. Various drugs. (F.D.C. No. 42315. S. Nos. 32-161/2 P, 32-165/6 P, 32-168/75 P.)

QUANTITY: 1 186-capsule btl. of *Compazine Spansules*, 1 180-tablet btl. of *Nilivar Salud*, 1 370-tablet btl. of *Premarin with methyltestosterone*, 1 62-capsule box of *Panalba*, 1 180-capsule btl. of *Vascutum*, 1 185-tablet btl. of *penicillin*, 1 100-tablet btl. of *Neopenzine 300*, 1 1-oz. btl. of *Cathomyacin Calcium Syrup*, 1 1-pt. btl. of *Tetrabon V Tetracycline Syrup*, 24 cartoned vials of *Remanden-100*, 6 cartoned vials of *Remanden-250*, and 4 24-tablet btl. of *Dramcillin-250* (penicillin with sulfonamides), at New York, N.Y., in possession of Theresa Pharmacy.

SHIPPED: The articles were shipped at various times in the past 5 years, prior to the filing of the libel from outside the State of New York.

RESULTS OF INVESTIGATION: The *Compazine Spansule capsules*, *Nilivar Salud tablets*, *Premarin tablets with methyltestosterone*, *Panalba capsules*, *Vascutum*

capsules, penicillin tablets, Neopenzine 300 tablets, Cathomylin Calcium Syrup, and Tetrabon V Tetracycline Syrup were repacked and labeled by the dealer after shipment as described above.

**LIBELED:** 1-2-59, S. Dist. N.Y.

**CHARGE:** *Cathomylin Calcium Syrup*. 501(c)—while held for sale, the strength of the article fell below that which it purported and was represented to possess, namely, that each 5 cc. contained 125 milligrams of novobiocin.

*Compazine Spansule capsules, Nilivar Salud tablets, Premarin tablets, with methyltestosterone, and Vascutum capsules*. 502(b) (2)—while held for sale, the labels of the articles failed to bear an accurate statement of the quantity of contents; and 502(e) (2)—their labels failed to bear the common or usual name of each active ingredient; and 503(b) (4)—the articles were subject to 503(b) (1) and their labels failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

*Ramanden-100, Remanden-250, and Dramcillin-250 tablets*. 502(1)—while held for sale, the articles were composed in part of a kind of penicillin and they were not from batches with respect to which certificates were effective since the drugs had passed their effective expiration dates.

*Panalba capsules, penicillin tablets, and Neopenzine-300 tablets*. 502(1)—while held for sale, the articles were composed in whole or in part of penicillin and they were not from batches with respect to which certificates or releases were effective pursuant to Section 507 since they were repackaged and had not been certified since repacking.

*Tetrabon V Tetracycline Syrup*. 502(1)—while held for sale, the article was composed in part of chlortetracycline and it was not from a batch with respect to which a certificate or release was effective pursuant to Section 507 since it was repackaged and had not been certified since repacking.

The libel also charged that a quantity of vitamin tablets was adulterated and misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

**DISPOSITION:** 1-27-59. Default—destruction.

## DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

### DRUGS FOR HUMAN USE

5866. Betaine hydrochloride and betaine anhydrous. (F.D.C. No. 43130. S. Nos. 38-986/8 P and 39-000 P.)

**QUANTITY:** 2 drums of *betaine hydrochloride* and 2 drums of *betaine anhydrous* at San Jose, Calif.

**SHIPPED:** 10-28-58 and 1-9-59, from New York, N.Y., by Polychemical Laboratories, Inc.

**LABEL IN PART:** (Drum) "10 Lbs. Betaine Hydrochloride for Manufacturing, Processing or Repacking. \* \* \* Polychemical Laboratories, Inc. \* \* \* New York 59, N.Y.," (drum) "25 Lbs. Betaine Anhydrous Lot 211 For Manufacturing, processing or repacking \* \* \* Polychemical Laboratories, Inc. \* \* \* New York, N.Y."

**LIBELED:** 5-6-59, N. Dist. Calif.

**CHARGE:** 502(f) (1)—when shipped, the labeling of the articles failed to bear adequate directions for use.

**DISPOSITION:** 6-4-59. Default—destruction.



5867. **Cabbage juice extract.** (F.D.C. No. 42320. S. No. 26-776 P.)

QUANTITY: 355 100-tablet btls. at Sioux City, Iowa.

SHIPPED: 7-7-58, from Redlands, Calif., by Vita Fluor Corp.

LABEL IN PART: "Vita Fluor Cabbage Juice Extract \* \* \* U-90 Manufactured by Vita Fluor Corporation \* \* \* Redlands, California \* \* \* Each tablet contains 400 Mg. of cabbage juice concentrate."

LIBELED: 11-20-58, N. Dist. Iowa: amended libel 4-24-59.

CHARGE: 502(f) (1)—when shipped, the labeling of the article failed to bear adequate directions for use for the purposes for which it was intended, namely, in the treatment of stomach and duodenal ulcers, which were the conditions for which the article was offered in a circular entitled "New Treatment for Gastric-Peptic Stomach and Duodenal Ulcers" disseminated by and on behalf of its manufacturer.

DISPOSITION: 6-30-59. Consent—destruction.

5868. **Vi-Arthra capsules.** (F.D.C. No. 43160. S. No. 53-101 P.)

QUANTITY: 10 100-capsule btls. at Los Angeles, Calif.

SHIPPED: The betaine hydrochloride component of the article was shipped on an unknown date from New York, N.Y., by Polychemical Laboratories, Inc., to San Francisco, Calif., and from there to San Jose, Calif., where it was used in the manufacture of the article. On 4-15-59, following its manufacture, the article was shipped to Los Angeles, Calif.

LABEL IN PART: (Btl.) "100 Capsules Vi-Arthra A Special Dietary Supplement \* \* \* Each Capsule Contains: Betaine 100 mg. Glycocyamine 25 mg. Glucuronolactone 40 mg."

LIBELED: 5-26-59, S. Dist. Calif.

CHARGE: 502(f) (1)—when shipped from New York, the labeling of the betaine hydrochloride component of the article failed to bear adequate directions for use.

DISPOSITION: 6-17-59. Default—destruction.

5869. **Aloe leaves and Papaya Rica.** (F.D.C. No. 42472. S. Nos. 55-861/2 P.)

INDICTMENT FILED: 7-2-59, W. Dist. Mo., against Lloyd C. Shanklin, t/a A-1 Harmony Health Foods and Juices, Kansas City, Mo.

ALLEGED VIOLATION: On 5-29-59, while quantities of *aloe leaves* and *Papaya Rica* were being held for sale by the defendant after shipment in interstate commerce, the defendant caused oral representations to be made regarding the purposes, conditions, and diseases for which the articles were intended; and also caused to accompany such articles, as labeling, a book entitled "Chemical Types of People and Their Foods," which acts resulted in the articles being misbranded.

CHARGE: 502(a)—the labeling of the articles, namely, the above-mentioned book, contained false and misleading representations that the *aloe leaves* were an adequate and effective treatment for stomach disorders, indigestion, gastritis, ulcers, piles and hemorrhoids, fistulas, tumors, cancer, kidney troubles, cataract, arthritis, external ulcers, stomach ulcers, colitis, diabetes, burns, bruises, sprains, boils, swelling of the joints, eczema, and athlete's foot, and that the *Papaya Rica* was an adequate and effective treatment for stomach disorders, indigestion, gastritis, ulcers, kidney troubles, stomach ulcers, colitis, and eczema; and 502(f) (1)—the labeling of the articles failed

to bear adequate directions for use for the purposes, conditions, and diseases for which they were intended, namely, (*aloe leaves*) as an adequate and effective treatment for X-ray burns, cancer, ulcers, piles, hemorrhoids, fistulas, and ivy poisoning, and (*Papaya Rica*) as an adequate and effective treatment for adding years to one's life, building up the heart, and for sleeping sickness, which were the purposes, conditions, and diseases for which the articles were held out orally by the defendant.

PLEA: Not guilty.

DISPOSITION: The case came on for trial before the court and jury on 9-21-59, and was concluded on the same day with the return of a verdict of guilty. On 10-2-59, the defendant was sentenced to 2 years in prison.

5870. Vince Dentifrice. (F.D.C. No. 42519. S. No. 32-525 P.)

QUANTITY: 252 2-oz. cartoned btls. and 120 5-oz. cartoned btls. at New York, N.Y.

SHIPPED: 10-6-58, from Morris Plains, N.J., by Standard Laboratories, Inc.

LABEL IN PART: (Ctn.) "Vince For Both Teeth and Gums \* \* \* Contains Sodium Borate Perhydrate, Calcium Phosphate Tribasic, Magnesium Trisilicate and Calcium Carbonate neutrally buffered with Sodium Aluminum Sulfate \* \* \* Distributed by Standard Laboratories, Inc., Morris Plains, N.J. 46563," (btl.) "Vince Oxygenating Dentifrice \* \* \* 110082 Distributed by Standard Laboratories, Inc., Morris Plains, N.J.," and (ctn. insert) "How the new, improved Vince keeps your mouth."

LIBELED: 12-12-58, S. Dist. N.Y.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for sore and bleeding gums, and for preventing trench mouth; 502(e) (2)—the article was a drug fabricated from two or more ingredients, and its label failed to list the active ingredient by its common or usual name, sodium perborate; and 502(f) (2)—the labeling of the article failed to warn that its use may cause irritation and inflammation of the gums, tongue, and mucous membranes of the mouth, and that use of the article should be discontinued at first sign of irritation or soreness, and that one should avoid swallowing the article.

DISPOSITION: 9-23-59. Default—destruction.

5871. Anterior pituitary and orchic solution. (F.D.C. No. 43115. S. No. 33-289 P.)

QUANTITY: 50 cartoned vials at Brooklyn, N.Y.

SHIPPED: 11-10-58, from Philadelphia, Pa., by Vitamix Corp.

LABEL IN PART: (Vial and ctn.) "Vitamix 30 cc. Multiple Dose Vial Orchic Anterior Pituitary Liquid \* \* \* For intramuscular Use Only \* \* \* Each 2 cc. contains the water soluble extraction of dried glands derived from: Orchic Substance, fresh gland . . . 10 gm. (155 grs.) Anterior Pituitary, Fresh gland . . . 1.12 gm. (18½ grs.) With Chlorobutanol (Chloral derivative) . . . 0.5% Contains no known hormonal therapeutic activity. Indications: Non-Specific Protein Therapy.

LIBELED: 5-5-59, E. Dist. N.Y.

CHARGE: 502(a)—when shipped, the label statement "Indications: Non-Specific Protein Therapy" was false and misleading as applied to an article

which is of no value in protein therapy; and 502(f) (1)—the labeling of the article failed to contain adequate directions for use since the article was worthless for any therapeutic purpose and no adequate directions for its use could be written.

DISPOSITION: 5-28-59. Default—destruction.

**5872. Anterior pituitary solution.** (F.D.C. No. 43114. S. No. 53-037 P.)

QUANTITY: 16 ctns., each containing 10 cartoned vials, at Huntington Park, Calif.

SHIPPED: 1-26-59, from Philadelphia, Pa., by Vitamix Corp.

LABEL IN PART: (Vial and ctn.) "30 cc. Multiple Dose Vial Anterior Pituitary Solution Sterile-Intramuscular Only \* \* \* Manufactured in Phila. for Daylin Drugs, Inc., Distributors, Huntington Park, Calif. Each cc. Contains the water soluble extraction of dried glands derived from: Anterior Pituitary, fresh gland . . . 18½ grains Chlorobutanol (Chloral deriv.) . . . 0.5% Contains no known hormonal therapeutic activity Indications: Non-Specific Protein Therapy. Usual Dose: \* \* \* Caution."

LIBELED: 4-16-59, S. Dist. Calif.

CHARGE: 502(a)—when shipped, the label statement "Indications: Non-Specific Protein Therapy" was false and misleading as applied to an article which is of no value in protein therapy; and 502(f) (1)—the labeling of the article failed to contain adequate directions for use since the article was worthless for any therapeutic purpose and no adequate directions for its use could be written.

DISPOSITION: 5-6-59. Default—destruction.

#### DRUGS FOR VETERINARY USE

**5873. Medicated feed.** (F.D.C. No. 43670. S. Nos. 47-553 P, 48-142 P.)

INFORMATION FILED: 12-7-59, W. Dist. N.Y., against Dean & Lee, a partnership, Horseheads, N.Y., and Harry L. Kahler, a partner.

SHIPPED: Between 9-13-58 and 2-13-59, from New York to Massachusetts.

LABEL IN PART: (Some bags) "100 Lbs. Net Pathfinder Medicated Jumbo Starter-Broiler \* \* \* Active drug ingredients: Nicarbazin 0.0125%," and other bags were unlabeled.

CHARGE: (Labeled bags) 501(d) (2)—a product containing acetyl-(p-nitrophenyl)-sulfanilamide and 3,5-dinitrobenzamide had been substituted for nicarbazin which the article was represented to be; and (unlabeled bags) 502(b)—the article failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; 502(e) (2)—the article failed to bear a label containing the common or usual name of each active ingredient; 502(f) (1)—the article failed to bear labeling containing adequate directions for use; and (2) adequate warnings against unsafe dosage or methods or duration of administration or application in such manner and form as are necessary for the protection of users.

PLEA: Guilty.

DISPOSITION: 1-4-60. Partnership—\$100 fine; individual—\$100 fine which was remitted.



5874. I.O.D. powder (F.D.C. No. 42500. S. No. 21-860 P.)

QUANTITY: 53 drums at Omaha, Nebr.

SHIPPED: Between 7-31-58 and 9-10-58, from St. Joseph, Mo., by Research Laboratories, Inc.

LABEL IN PART: "Peters 25 Pound I.O.D. Powder For Veterinary Use Only Each Ounce Contains: Ethylenediamine dihydroiodide 4.6% \* \* \* Sodium chloride and Color q.s. Supplies readily available iodine, liberated internally as Hydriodici Acid, in therapeutic dosage \* \* \* Peters Serum Co. Laboratories Kansas City, Missouri."

RESULTS OF INVESTIGATION: Examination showed that the article was a reddish crystalline powder containing approximately 3.92 percent iodine, or about 4.88 percent of ethylenediamine dihydroiodide.

LIBELED: 11-21-58, Dist. Nebr.

CHARGE: 502(a)—the label of the article, when shipped, contained false and misleading representations that the article was an adequate and effective treatment for sterility, mastitis and ketosis in cattle; and 502(f)(1)—the labeling of the article failed to bear adequate directions for use in the treatment of agalactia and cervical abscesses in swine which were the conditions for which the article was recommended in its labeling and for which no directions for use appeared on the labeling.

DISPOSITION: 12-30-58. Default—destruction.

#### DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS\*

5875. Thyroid tablets and thyroid-digitalis tablets. (F.D.C. No. 42551. S. Nos. 23-389/90 P.)

QUANTITY: 4 ctns., each containing 27, 625 *thyroid-digitalis tablets* and 6 ctns., each containing 16,317 *thyroid tablets* at Las Vegas, Nev.

SHIPPED: 9-19-58 and 10-16-58, from Sun Valley, Calif., by J. L. Jones & Co.

LABEL IN PART: "J. L. Jones & Company \* \* \* 7200 Vineland Ave., Sun Valley, California Manufacturing Chemists \* \* \* Each tablet contains: Thyroid U.S.P. 3 grains Digitalis Leaves Powder  $\frac{3}{4}$  grain" [or "Each tablet contains: Thyroid 5 Grains"]."

RESULTS OF INVESTIGATION: The *thyroid-digitalis tablets* contained 75 percent of the labeled amount of thyroid and 57 percent of the labeled potency of digitalis per tablet, and the *thyroid tablets* contained 60 percent of the labeled amount of thyroid per tablet.

LIBELED: 12-9-58, Dist. Nev.

CHARGE: 501(b)—when shipped, the strength of the *thyroid tablets* differed from the standard set forth in the United States Pharmacopeia; 501(c)—the strength of the *thyroid-digitalis tablets* differed from that which they purported and were represented to possess; and 502(a)—the statements on the labels of the articles, namely, "Each tablet contains: Thyroid 5 grains" and "Each tablet contains Thyroid U.S.P. 3 grains \* \* \* Digitalis Leaves Powder  $\frac{3}{4}$  grain" were false and misleading.

DISPOSITION: 1-16-59. Default—destruction.

\*See also Nos. 5862, 5863, 5865, 5873.

**5876. Super Rybutol gelucaps.** (F.D.C. No. 42560. S. No. 24-426 P.)

QUANTITY: 220 60-capsule btl. at Los Angeles, Calif.

SHIPPED: Between 2-3-58 and 6-13-58, from St. Louis, Mo.

RESULTS OF INVESTIGATION: Examination showed that the article contained approximately 80 percent of the declared amount of vitamin B<sub>1</sub>.

LIBELED: 12-31-58, S. Dist. Calif.

CHARGE: 501(c)—while held for sale, the strength of the article differed from that which it purported and was represented to possess, namely, 15 milligrams of vitamin B<sub>1</sub> per capsule; and 502(a)—the labeling of the article contained false and misleading representations that it was an effective treatment for loss of energy, lack of appetite, nervousness, and indigestion.

The libel alleged also that certain other quantities of Rybutol capsules were adulterated and misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 1-26-58. Default—destruction.

**5877. Dex-All capsules.** (F.D.C. No. 42601. S. No. 24-515 P.)

QUANTITY: 11 1,000-capsule btl., 2 500-capsule btl., and 40 100-capsule btl., at North Hollywood, Calif.

SHIPPED: 9-22-58, from Rensselaer, N.Y., by Delmar Pharmacal Corp.

LABEL IN PART: (Bulk container) "Del-Bardex #1 Timed Disintegration Capsule Each Capsule contains Dextro Amphetamine Sulfate 10 Mg. Amobarbital 60 Mg. \* \* \* in a Special Base That Provides for the Disintegration of the Contents Throughout a Period of About 6-10 Hours \* \* \* 25,000 Capsules, \* \* \* Delmar Pharmacal Co., \* \* \* Rensselaer, New York."

The capsules were repackaged into bottles from bulk stock as labeled above.

RESULTS OF INVESTIGATION: Analysis showed that the article contained labeled amounts of dextro-amphetamine sulfate and amobarbital of which 75 percent of the dextro-amphetamine sulfate was released in two hours.

LIBELED: 1-12-59, S. Dist. Calif.

CHARGE: 501(c)—when shipped, the quality of the article differed from that which it was purported or represented to possess in that it failed to disintegrate at a uniform rate over a 6 to 10 hour period; and (502(a)—the label statement "in a Special Base That Provides for the Disintegration of the Contents throughout a Period of About 6-10 hours" was false and misleading.

DISPOSITION: 2-5-59. Default—destruction.

**5878. Contact lens wetting solution.** (F.D.C. No. 43178. S. Nos. 57-699/700 P.)

QUANTITY: 480 2-oz. btl. and 2,000 5-cc. btl. at New York, N.Y.

SHIPPED: 2-13-59, from Wauconda, Ill., by Mi-Con Laboratories.

LABEL IN PART: (Btl.) "UCL Wetting Solution An antiseptic, wetting and cleansing solution to be used with plastic contact lenses. Directions: \* \* \* Active ingredients: Alkyl dimethyl benzyl ammonium chloride 1:25000 distributed by United Contact Lens Corp. 76 Madison Ave., New York 16, N.Y." or "5 cc. \* \* \* UCL Wetting Solution Directions \* \* \* distributed by United Contact Lens Corp. 76 Madison Ave., New York 16, N.Y."

RESULTS OF INVESTIGATION: Examination showed that the article was contaminated with large numbers of viable micro-organisms.

LIBELED: 7-14-59, S. Dist. N.Y.

**CHARGE:** 501(c)—when shipped, the purity and quality of the article fell below that which it purported and was represented to possess, since it purported to be suitable for use in the eye and for cleaning contact lenses and rendering them free from microbial contamination; whereas it was not suitable for such uses and purposes since it was contaminated with large numbers of viable micro-organisms.

**DISPOSITION:** 8-5-59. Default—destruction.

**5879. Rectal thermometers.** (F.D.C. No. 42539. S. No. 32-231 P.)

**QUANTITY:** 264 rectal thermometers in envelopes at Englewood, N.J.

**SHIPPED:** 10-7-58, from Brooklyn, N.Y., by Adelphi Surgical Co., Inc.

**LABEL IN PART:** (Envelope) "Certificate of Examination Fever Thermometer \* \* \* issued by the United States Dept. of Commerce Comet Thermometer Co., Brooklyn, N.Y. [or Cardinal Thermometer Co., Brooklyn, N.Y.]" and (engraved on thermometer) "Adelco Rectal."

**RESULTS OF INVESTIGATION:** Examination of 24 thermometers showed that 13 failed to meet the requirement for accuracy specified in CS1-52, issued by the National Bureau of Standards, when tested as described in CS1-52.

**LIBELED:** 12-5-58, Dist. N.J.

**CHARGE:** 501(c)—when shipped, the quality of the article fell below that which it purported and was represented to possess since it did not give accurate readings; and 502(a)—the label statement "tested and found to meet all the requirements and tests specified in the Commercial Standard CS1-52" was false and misleading.

**DISPOSITION:** 1-12-59. Default—destruction.

**5880. Rubber prophylactics.** (F.D.C. No. 42695. S. No. 45-221 P.)

**QUANTITY:** 93 12-box ctns., each box containing 12 prophylactics, at Salt Lake City, Utah.

**SHIPPED:** 10-13-58, from North Kansas City, Mo., by Dean Rubber Mfg. Co.

**LABEL IN PART:** (Ctn.) "Peacocks The Original Reservoir Ends \* \* \* Redi-Wet Rubbers in Foil \* \* \* Dean Rubber Mfg. Co. North Kansas City, Mo.," (box) "Peacocks Redi-Wet Rubbers in Foil."

**RESULTS OF INVESTIGATION:** Examination of 288 prophylactics showed that 1.4 percent were defective since they contained holes.

**LIBELED:** 2-17-59, Dist. Utah.

**CHARGE:** 501(c)—the quality of the article, when shipped, fell below that which it purported to possess.

**DISPOSITION:** 4-24-59. Default—condemnation.

## DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

### DRUGS FOR HUMAN USE\*

**5881. Arman's ear drops.** (F.D.C. No. 42380. S. No. 27-319 P.)

**QUANTITY:** 40 btls. at Des Moines, Iowa.

**SHIPPED:** Between 8-29-58 and 10-14-58, from Omaha, Nebr., by Arman Drug Co., Inc.

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\*See also Nos. 5864, 5869-5872, 5875-5877, 5879.



**LABEL IN PART:** (Btl.) "Contents 15 C.C. \* \* \* Arman's Ear Drops \* \* \* Manufactured by Arman Drug Co., Inc., Omaha, Nebraska, Formula: Benzalkonium Chloride 1:1,000 Chlorabutanol (anhydrous) 1% Benzocaine and Urea in Propylene Glycol and Glycerine Base."

**LIBELED:** 12-1-58, S. Dist. Iowa.

**CHARGE:** 502(a)—the label of the article, when shipped, contained false and misleading representations that the article was an adequate and effective treatment for ear infections and earache.

**DISPOSITION:** 1-5-59. Consent—destruction.

**5882. Meducrin cream and Meducrin lotion.** (F.D.C. No. 42292. S. No. 2-317 P.)

**QUANTITY:** 2,200 boxes, each containing 1 cartoned bottle of lotion and 1 cartoned tube of cream, at Miami Beach, Fla., in possession of Hartel, Inc.

**SHIPPED:** 5-16-58, from West Germany.

**LABEL IN PART:** (Btl.) "Meducrin Lotion For Hair Grooming and Removal of Dandruff Scales \* \* \* distributed in the U.S.A. by: Hartel Inc. \* \* \* Contents 7 Fluid Ounces," (tube) "Meducrin Cream for Hair Grooming and Removal of Dandruff Scales \* \* \* Distributed in the U.S.A. by: Hartel Inc. \* \* \* Contents: 2½ ounces."

**ACCOMPANYING LABELING:** Circular letter entitled "Meducrin \* \* \* Dear Friend."

**RESULTS OF INVESTIGATION:** Analysis showed that the article was a clear, yellow-colored, perfumed liquid containing some sediment and composed essentially of isopropyl alcohol, menthol, glandular extract, resorcinol, and perfume. The above-mentioned circular letter was printed at the request of the dealer.

**LIBELED:** 11-13-58, S. Dist. Fla.

**CHARGE:** 502(a)—the labeling accompanying the article, while held for sale, contained false and misleading representations that the article was an adequate and effective treatment for overcoming dandruff and baldness, stopping falling hair, growing hair, and curing scalp sores and itchy scalp.

**DISPOSITION:** 12-9-58. Hartel, Inc., claimant, having consented to the condemnation of the article and to the entry of an injunction, a decree was entered condemning the article and permanently enjoining the claimant against introducing into interstate commerce any article similar to that under seizure which is accompanied by labeling containing the representations indicated above, and against doing any act with respect to such article, while held for sale after shipment in interstate commerce, which would result in the article being accompanied by labeling containing such representations. In accordance with the consent decree, the article was released under bond and relabeled.

**5883. Bergman's mixture.** (F.D.C. No. 42547. S. No. 42-112 P.)

**QUANTITY:** 897 pt. btls. and 386 qt. btls. at Portland, Oreg.

**SHIPPED:** Between 5-26-58 and 6-27-58, from Seattle, Wash., by Bergman Drug Mfg. Co.

**LABEL IN PART:** "Bergman's Mixture \* \* \* Active Ingredients: Bismuth Subnitrate, Bismuth Subgallate, Milk of Magnesia, Peppermint with sodium Benzoate 0.2% Directions \* \* \* Manufactured exclusively for Bergman Drug Manufacturing Co. \* \* \* Renton, Washington."

ACCOMPANYING LABELING: Placards entitled "Bergman's Mixture Guarantees" and "Immediate Relief."

LIBELED: 12-12-58, Dist. Oreg.

CHARGE: 502(a)—the labeling accompanying the article, when shipped, contained false and misleading representations that the article was an adequate and effective treatment for stomach ulcers and other stomach disorders.

DISPOSITION: 1-12-59. Consent—claimed by Harold K. Thevik, Trustee in Dissolution of Bergman Drug Mfg. Co. and relabeled.

5884. Teen-Clear. (F.D.C. No. 42556. S. No. 26-298 P.)

QUANTITY: 1,436 combination pkgs., each containing 1 btl. and 1 cartoned tube, at Minneapolis, Minn.

SHIPPED: 9-30-58, from Madrid, Iowa, by P-M Laboratories, Inc., of Hampton, Iowa.

LABEL IN PART: (Btl.) "Medically Approved Teen Clear \* \* \* Net Contents 4 Oz. \* \* \* Active Ingredients: Hexachlorophene, Azulene"; (tube and ctn.) "Teen Clear Gel \* \* \* Active Ingredients: Menthol, Resorcinol, Phenol, (1:1000) Boric Acid, in a complete water soluble base. \* \* \* Net. Wt. 1 Oz."

ACCOMPANYING LABELING: Carton insert entitled "Helpful Hints on Treating Pimples and Acne" and a display stand entitled "New! Medically Approved Teen-Clear Rids Pimples-Acne."

RESULTS OF INVESTIGATION: The article in the bottles consisted chiefly of isopropyl alcohol. No examination was made to determine the presence of the other ingredients declared on the bottle label or of the ingredients of the article in the tubes.

LIBELED: 12-11-58, Dist. Minn.

CHARGE: 502(a)—the labeling of the article, when shipped, contained false and misleading representations that the article was an adequate and effective treatment for pimples and acne; and 502(e)(2)—the article in the bottles contained isopropyl alcohol and its label failed to bear the quantity, kind, and proportion of alcohol therein.

DISPOSITION: 2-27-59. Default—destruction.

5885. Elma Health Tea. (F.D.C. No. 42569. S. No. 32-973 P.)

QUANTITY: 219 cases, 24 4-oz. boxes each, at Bronx, N.Y., in possession of Ripet Products Co., Inc.

SHIPPED: 2-24-58, from outside the United States.

LABEL IN PART: (Box) "Elma Health Tea Imported Wild Rose Hips From Europe. These berries are dried and cut for tea bag size \* \* \* Contents: 24 Tea Bags \* \* \* Distributors: Ripet Products Co., Inc."

RESULTS OF INVESTIGATION: The article was repacked from bulk stock into the above-mentioned boxes after shipment as described above.

LIBELED: 1-14-59, S. Dist. N.Y.

CHARGE: 502(a)—while held for sale, the label of the article contained false and misleading representations that the article was an adequate and effective treatment for disorders of the kidneys, liver, bladder, and gall bladder, and a source of building strength in the convalescent.

DISPOSITION: 2-2-59. Default—destruction.

**5886. Sulfur bath concentrate.** (F.D.C. No. 42803. S. No. 36-515 P.)

QUANTITY: 522 8-oz. btls. at St. Louis, Mo., in possession of Po-Gi Enterprises.

SHIPPED: 7-31-58 and 8-8-58, from Chicago, Ill., by As You Were Associates.

LABEL IN PART: (Btl.) "Paul's Sulfur Bath Concentrate \* \* \* As You Were Associates Distributor. \* \* \* Chicago."

ACCOMPANYING LABELING: Leaflets entitled "The Miracle of Natural Sulfur Bath," "Historical Medicine The History of Bathing," and "Ancient Mystery Solved"; and a letter entitled "Did The Ancients Unlock Nature's Own Secret of the Wellspring of Youth?"

RESULTS OF INVESTIGATION: The leaflets entitled "Ancient Mystery Solved" were printed locally for the dealer and the other accompanying labeling was shipped to the dealer by As You Were Associates.

LIBELED: 1-23-59, E. Dist. Mo.; amended libel, 2-3-59.

CHARGE: 502(a)—when shipped and while held for sale, the labeling contained false and misleading representations that the article was an adequate and effective treatment for arthritis, rheumatism, acne, psoriasis, other skin disorders, nervous tension, tiredness, bursitis, sciatica, swollen aching joints, pimples, blotches on skin, boils, and dermatitis.

DISPOSITION: 3-3-59. Default—destruction.

**5887. Minerals.** (F.D.C. No. 42787. S. No. 1-352 P.)

QUANTITY: 10 lbs. in bulk at Pensacola, Fla., in possession of J. A. Barrett.

SHIPPED: May 1958, from Calhoun, Ga.

LABEL IN PART: (Retail label) "Genuine Blue Ridge Mountain Minerals Carbonate of Calcium, 10.063; Sulphate of Potassium, 1.54; Carbonate of Strontium, 0.123; Sulfate of Sodium, 1.12; Carbonate of Sodium, 1.12; Sulphate of Iron, 9.12; Carbonate of Magnesium, 1.03; Organic Matter, 1.54; Carbonate of Iron, 68.87; Chloride of Sodium, 2.20; Carbonate of Lithium, 1.26; Sulphate of Silica, 1.46; Sulphate of Magnesium, 3.67."

ACCOMPANYING LABELING: Circular reading in part "What Genuine Blue Ridge Mountain Minerals will do for you."

RESULTS OF INVESTIGATION: In the normal course of dealer's business the articles were repacked in 6-oz. packages and labeled as described above.

LIBELED: 1-14-59, N. Dist. Fla.

CHARGE: 502(a)—while held for sale, the labeling contained false and misleading representations that the article was an adequate and effective treatment for "high blood pressure, pellagra, nervousness, inability to sleep, nervous 'indigestion', rheumatism, kidney and bladder trouble, piles, sore eyes, blood poison, and all skin infections," erysipelas or Tetta Flux, female complaints and all blood disease, loss of appetite, old sores and bed wetting, 'pyriear' of the gums, athletic feet, sugar diabetea," and as a body builder and blood purifier.

DISPOSITION: 2-20-59. Default—destruction.

**5888. Hairnow Herbal Hair Tonic.** (F.D.C. No. 42788. S. No. 14-165 P.)

QUANTITY: 8 btls. and 11 display ctns., 12 btls. each, at South Bend, Ind.

SHIPPED: Between 9-10-58 and 10-10-58, from Detroit, Mich., by Active Therapy Products Co.



**LABEL IN PART:** (Display ctn.) "Hairnow \* \* \* For Men and Women \* \* \* Active Therapy Products Co. \* \* \* New York 1, New York," (btl.) "Hairnow \* \* \* Contents 4 Oz. Herbal Hair Tonic Active Ingredients: Acidum Boricum 1 grain, African Capsicum annum, Althaea officinalis, Arcitum Lappa, Avena Sativa, Menthol (Laevo), Pilocarpine Hydrochloride (Indian Hemp) ½ grain Rosemarinus officinalis, Sodium Borate tetra, Tri-Sodium ethyl-ethylenediamine tri acetic (Na3EDTA) Urtica dioica 8% \* \* \* Formulated, Manufactured and Distributed by Active Therapy Products Co., Detroit, Michigan."

**ACCOMPANYING LABELING:** Advertisement card reading in part "Save Your Hair" and an advertisement sheet reading in part "Save Your Hair \* \* \* Satisfaction Guaranteed—Or your Money Back."

**LIBELED:** 1-15-59, N. Dist. Ind.

**CHARGE:** 502(a)—the labeling of the article, when shipped, contained false and misleading representations that the article was an adequate and effective treatment for the prevention and cure of baldness and for nourishing the hair.

**DISPOSITION:** 3-6-59. Default—destruction.

**5889. Vibrating cushion.** (F.D.C. No. 42059. S. Nos. 18-351/2 P.)

**QUANTITY:** 9 devices individually cartoned at Price and Moab, Utah.

**SHIPPED:** 4-18-58 and 5-16-58, from Denver, Colo., by Vibra Mfg. Corp.

**LABEL IN PART:** (Device) "VIBRA MFG. CORP. MAKES REDUCE-O-PAD WORLD'S FINEST MASSAGE CUSHION," (ctn.) "ANOTHER REDUCE-O-PAD BY VIBRA MFG. CORP."

**ACCOMPANYING LABELING:** Leaflets entitled, "REDUCE-O-PAD GUARANTEE," "POINTERS ON THIS THE ORIGINAL," "THE HEART . . . CIRCULATION," "THE COMPLETE WAY TO RELAXATION" and "REDUCE-O-PAD."

**RESULTS OF INVESTIGATION:** The article was of box construction, 12" by 14" by 4", upholstered with foam rubber, and containing an electric motor providing vibration.

**LIBELED:** 7-23-58, Dist. Utah.

**CHARGE:** 502(a)—when shipped, the labeling contained false and misleading representations that the device was an adequate and effective treatment for revitalizing work-weary nerves and muscles; relief of cramps during difficult times of the month; spot reducing; arthritis; rheumatism; bursitis; swelling of the joints; muscular aches and pains; backaches; headaches; nervousness; hypertension; relaxing nervous tension of the heart and other organs; stimulating local circulation; breaking down fatty tissues, and reducing weight.

**DISPOSITION:** 3-13-59. Consent—claimed by Vibra Mfg. Corp. and relabeled.

**5890. Vibrating pillows.** (F.D.C. No. 42517. S. No. 17-291 P.)

**QUANTITY:** 10 devices at Louisville, Ky.

**SHIPPED:** 9-5-58, from Columbus, Ohio, by R. G. Barry Corp.

**ACCOMPANYING LABELING:** Label card enclosed with device reading in part "Reduce and Relax with Vibraway by Barry."

**RESULTS OF INVESTIGATION:** The device consisted of corduroy-covered, foam rubber-filled, pillows containing an electric motor capable of providing vibration.

**LIBELED:** 12-3-58, W. Dist. Ky.

**CHARGE:** 502(a)—the labeling accompanying the devices, when shipped, contained false and misleading representations that the devices were an adequate and effective treatment for weight reducing, trimming inches away, making “tensions just disappear,” removing fatty tissues to make hips slimmer, and firming up sagging stomach muscles.

**DISPOSITION:** 2-13-59. Default—delivered to Food and Drug Administration.

**5891. Bel-Air vibrating lounge.** (F.D.C. No. 42535. S. No. 28-838 P.)

**QUANTITY:** 24 individually cartoned devices at Shreveport, La., in possession of Bel-Air Distributors.

**SHIPPED:** 9-16-58 and 10-16-58, from Los Angeles, Calif., by Health Appliances Corp.

**LABEL IN PART:** (Device) “The Bel-Air Lounge Manufactured by Health Appliances Corp.”

**ACCOMPANYING LABELING:** Leaflet in carton entitled “How to Have and Hold a Slender Livelier Figure,” and other leaflets entitled “The Lounge of Tomorrow.”

**RESULTS OF INVESTIGATION:** The article was a table or lounge-type vibrator device. The electric motor was contained in a housing on which an upholstered vibrating cushion was mounted. Padded tubular extensions could be attached to the housing to provide support for the body. The leaflets entitled “The Lounge of Tomorrow” were printed locally at the dealer’s request.

**LIBELED:** 12-8-58, W. Dist. La.

**CHARGE:** 502(a)—when shipped and while held for sale, the labeling accompanying the article contained false and misleading representations that the article was an adequate and effective treatment for slenderizing and spot reducing, relaxing nerves, toning the system, firming and tightening sagging muscles, reportioning the figure, and reducing weight.

**DISPOSITION:** 3-13-59. Consent—claimed by W. C. Wheat, Shreveport, La., and relabeled.

**5892. Contour chairs.** (F.D.C. No. 42559. S. Nos. 11-564 P, 13-581 P.)

**QUANTITY:** 51 *contour chairs* at Milwaukee, Wis., in possession of James C. Carney, t/a Contour Lounge Shop.

**SHIPPED:** During 1958, from St. Louis, Mo., by Contour Chair-Lounge Co., Inc.

**LABEL IN PART:** “Contour Chair Lounge Co., Inc., St. Louis, Mo. with Vibrator Model \* \* \* Serial \* \* \*.”

**ACCOMPANYING LABELING:** Booklets entitled “A Practical Guide”; wall placards and leaflets entitled “New! A Contour Exclusive!”; and envelopes containing newspaper advertisement tear sheets.

**RESULTS OF INVESTIGATION:** The article was an upholstered lounge or reclining-type, adjustable chair containing an electric motor capable of providing vibration; in addition, six of the chairs contained a rheostatically-controlled heating element. The above-mentioned tear sheets were prepared by the dealer and the other accompanying labeling was purchased by the dealer from the shipper.

**LIBELED:** 12-10-58, E. Dist. Wis.

**CHARGE:** 502(a)—the labeling accompanying the article, when shipped and while held for sale, contained false and misleading representations that the chairs were an adequate and effective treatment for reducing heart strain; penetrating every nerve center to relax the nervous tensions of the body's organs; overcoming circulatory and nervous ailments; easing pain and preventing distortion of the spine; relieving backaches, arthritis, rheumatism, sciatica, sore muscles, swollen limbs, poor circulation, asthma, heart conditions and breathing trouble; stimulating mental activity; and reviving energy.

**DISPOSITION:** 1-7-59. Consent—claimed by James C. Carney, t/a Contour Lounge Shop, and relabeled.

**5893. Figure Trim Contour Pads.** (F.D.C. No. 42635. S. Nos. 38-626/7 P.)

**QUANTITY:** 48 small and 12 large devices, individually cartoned, at Brockport, N.Y.

**SHIPPED:** 12-6-58, from Little Rock, Ark. This was a return shipment.

**LABEL IN PART:** (Device) "Figure Trim Contour Rest Manufactured by San Joy Mfg. Co., Brockport, N.Y."

**ACCOMPANYING LABELING:** Leaflets in carton entitled "Operating Instructions."

**RESULTS OF INVESTIGATION:** The article was an upholstered, semi-rigid, cushion-type device containing an electric motor capable of providing vibration.

**LIBELED:** 12-10-58, W. Dist. N.Y.

**CHARGE:** 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for relief of rheumatism, bursitis, arthritis, and other painful side effects of these types of illnesses, firming and toning the body, increasing circulation to carry away fatty deposits in the blood, and for reducing weight.

**DISPOSITION:** 3-5-59. Consent—claimed by San Joy Mfg. Co. and relabeled.

**5894. Handy-Hannah massager.** (F.D.C. No. 42652. S. No. 27-514 P.)

**QUANTITY:** 20 individually cartoned devices at Minneapolis, Minn.

**SHIPPED:** 11-17-58, from Whitman, Mass., by Handy-Hannah Products Corp.

**LABEL IN PART:** (Ctn.) "Handy-Hannah all purpose massager \* \* \* magic vibrating disc," (device) "Handy-Hannah Electric Vibrator."

**ACCOMPANYING LABELING:** Leaflet entitled "Look At What Your Handy-Hannah Magic Disc Vibrator Can Do." Catalog containing advertisement reading in part "Handy-Hannah Big 8½" All Purpose Disc Vibrator-Massager."

**RESULTS OF INVESTIGATION:** The article was an 8½ inch, disc-shaped, convex-surfaced device equipped with grip handle and containing an electric motor capable of providing vibration.

**LIBELED:** 12-23-58, Dist. Minn.

**CHARGE:** 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for reducing unwanted curves, replacing "fatty tissues with a slimmer, sleeker look," toning and firming body tissues, controlling weight on stomach and abdomen, slimming excess weight from hips, and slenderizing inaccessible parts of the body.

**DISPOSITION:** 2-27-59. Default—delivered to Food and Drug Administration.



**5895. Vimulator device.** (F.D.C. No. 42776. S. No. 24-694 P.)

**QUANTITY:** 20 devices at Glendale, Calif.

**SHIPPED:** 9-10-58, from Portland, Oreg., by the Bullock Vimulator Co.

**LABEL IN PART:** "Wings For Your Feet The Vimulator Timesaving Exerciser for the Foot \* \* \* Manufactured by Bullock Vimulator Co. P.O. Box 4963, Portland, Oregon."

**ACCOMPANYING LABELING:** Leaflets entitled "Six Magic Vimulator Footsteps," "Footprints—Good News," "Mother Nature—The best surgeon," "Manipulative Technique," "The Vimulator System," "Get Acquainted with your Feet!," "Bunions! Callouses!," "Foot Trouble," "More Proof," and "Foot Chart."

**RESULTS OF INVESTIGATION:** Examination showed that the article was a covered hardwood platform or board, padded with sponge rubber. The sponge rubber was armed with hard rubber to form three bumps in the contour of the device.

**LIBELED:** 1-12-59, S. Dist. Calif.

**CHARGE:** 502(a)—the labeling accompanying the article, when shipped, contained false and misleading representations that the article was an adequate and effective treatment for raising fallen or broken arches; relieving and correcting bunions; removing causes of tender, sore feet, warts, callouses, and soft corns; restoring misplaced instep bones and tendons; improving circulation so as to be beneficial in cases of swollen ankles, cramps, varicose veins; reducing danger of falls; building a better balance and posture; eliminating cramps; streamlining the ankle and leg; realigning arch bones; relieving congestion in the foot; improving foot nourishment and bone repair; removing waste material between joints; straightening the spine; relieving backache; reducing legs, hips, and abdomen; and relieving pain of calcium spurs.

**DISPOSITION:** 2-5-59 and 2-25-59. Default—delivered to Food and Drug Administration.

**5896. Vibrating devices.** (F.D.C. No. 42330. S. No. 28-834 P.)

**QUANTITY:** 22 devices at New Orleans, La.

**SHIPPED:** 8-21-58, from Beacon, N.Y., by Bobrich Products Corp.

**LABEL IN PART:** "Bobrich Salon Vibrator—Manufactured by Bobrich Products Corp. 1 E. Main St., Beacon, N.Y."

**ACCOMPANYING LABELING:** Newspaper advertisement mat and tear sheets.

**RESULTS OF INVESTIGATION:** The devices consisted of upholstered solid frame cushions, each containing a heating element and electric motor capable of providing vibration.

The newspaper mat was furnished by the shipper and was used in preparing the newspaper advertisement contained in the tear sheets.

**LIBELED:** 10-22-58, E. Dist. La.

**CHARGE:** 502(a)—the labeling accompanying the devices, when shipped and while held for sale, contained false and misleading representations that the devices were an adequate and effective treatment for relieving nervous tension, increasing blood circulation, and overcoming arthritis, rheumatism, lumbago, backaches, and stiff neck.

**DISPOSITION:** 1-12-59. Consent—claimed by City Stores Co., t/a Maison Blanche, New Orleans, La., and relabeled.

**5897. Slenda-Matic devices.** (F.D.C. No. 42329. S. Nos. 14-198/9 P.)

**QUANTITY:** 8 contour devices and 1 rectangular device at Detroit, Mich.

**SHIPPED:** 7-28-58, from Chicago, Ill., by the Grayline Co.

**LABEL IN PART:** (Ctn.) "Holloco Slenda-Matic Distributed by S. S. Rolender Inc., Chicago, Illinois," (metal plate on device) "Slenda-Matic Manufactured by the Grayline Company, Chicago 33, Illinois \* \* \* Serial No."

**ACCOMPANYING LABELING:** Leaflet in carton entitled "Holloco Slenda-Matic Vibrating Machine."

**RESULTS OF INVESTIGATION:** The device was a wood frame box upholstered with polyurethane foam and covered with vinyl material. There was enclosed in the box a rheostat-controlled electric motor providing vibration.

**LIBELED:** 10-20-58, E. Dist. Mich.

**CHARGE:** 502(a)—the labeling of the device, when shipped, contained false and misleading representations that the device was capable of providing an adequate and effective treatment for improving circulation, easing tension, reducing weight, regaining a firm, trim, slender figure, and removing fatty tissue.

**DISPOSITION:** 12-17-58. Default—destruction.

#### DRUGS FOR VETERINARY USE\*

**5898. Piperazine wormer.** (F.D.C. No. 42365. S. No. 21-735 P.)

**QUANTITY:** 49 cases, 12 cans each, at Kansas City, Mo., in possession of Columbian Hog & Cattle Powder Co.

**SHIPPED:** 9-30-58, from Kansas City, Kans.

**LABEL IN PART:** (Can) "Columbian Piperazine Wormer For Swine, Poultry and Horses Expels Large Roundworms—Active Drug Ingredient: Piperazine Dihydrochloride 100%."

**ACCOMPANYING LABELING:** Folders entitled "Columbian Piperazine Wormer."

**RESULTS OF INVESTIGATION:** The folders were prepared by the dealer.

**LIBELED:** On or about 11-21-58, W. Dist. Mo.

**CHARGE:** 502(a)—the labeling accompanying the article, while held for sale, contained false and misleading representations that the article was an adequate and effective treatment for removing cecal worms from poultry.

**DISPOSITION:** 1-13-59. Default—the folders were destroyed and the article was delivered for the use of a municipal institution.

**5899. Iocine.** (F.D.C. No. 42614. S. No. 21-680 P.)

**QUANTITY:** 27 btl. at Omaha, Nebr.

**SHIPPED:** 6-1-58, from Kansas City, Mo., by Haver-Lockhart Laboratories.

**LABEL IN PART:** (Btl.) "R/I 987 1 Lb. \* \* \* Iocine Iodinated Casein Having Thyroid Activity by Virtue of its Thyroxin Content Contains: A Compound of Iodine and Casein \* \* \* Distributed by Haver-Glover Laboratories, Kansas City, Mo."

**ACCOMPANYING LABELING:** Copies of the September-October 1958 issue of "Haver-Lockhart Laboratories Messenger."

**LIBELED:** 12-3-58, Dist. Nebr.

\*See also Nos. 5863, 5874.

**CHARGE:** 502(a)—the labeling accompanying the article, when shipped, contained false and misleading representations that the article was a thyroprotein and would aid in increasing the fertility in rams and boars and better growth of swine and poultry.

**DISPOSITION:** 12-17-58. Consent—destruction.

**5900. Electronic generator device.** (F.D.C. No. 41806. S. No. 25-238 P.)

**QUANTITY:** 8 devices at St. Paul, Minn., in possession of Mastitis Control, Inc.

**SHIPPED:** 4-21-58, from Racine, Wis.

**ACCOMPANYING LABELING:** Leaflets designated "Mastitis Control Incorporated Presents The Hovde Method."

**RESULTS OF INVESTIGATION:** The leaflets were printed in St. Paul, Minn., for the dealer.

The device consisted of a type of electronic high frequency generator which produced a glow discharge in a variety of gas-filled glass applicators.

**LIBELED:** 6-13-58, Dist. Minn.

**CHARGE:** 502(a)—while held for sale, the labeling accompanying the article contained false and misleading representations that the article was an adequate and effective treatment for the prevention, control, and cure of mastitis in dairy cattle, and for blackhead in turkeys.

**DISPOSITION:** 3-7-59. Default—delivered to the Food and Drug Administration.



## INDEX TO NOTICES OF JUDGMENT D.D.N.J. NOS. 5861 TO 5900

## PRODUCTS

	N.J. No.		N.J. No.
Aloe leaves.....	<sup>1</sup> 5869	Medicated feed.....	5873
Anterior pituitary and orchic solution.....	5871	Meducrin cream.....	5882
solution.....	5872	lotion.....	5882
Antiseptic nasal spray.....	5864	Minerals.....	5887
Arman's ear drops.....	5881	Nasal spray, antiseptic.....	5864
Arthritis, remedies for. <i>See</i> Rheumatism, remedies for.		Neopenzine 300 tablets.....	5865
Barnes-Hind Wetting Solution..	5862	Neuralgia, remedies for. <i>See</i> Rheumatism, remedies for.	
Bel-Air vibrating lounge.....	5891	Neuritis, remedies for. <i>See</i> Rheumatism, remedies for.	
Bergman's mixture.....	5883	Nilivar Salud tablets.....	5865
Betaine anhydrous.....	5866	Panalba capsules.....	5865
hydrochloride.....	5866	Papaya Rica.....	<sup>1</sup> 5869
Bursitis, remedies for. <i>See</i> Rheumatism, remedies for.		Penicillin tablets.....	5865
Cabbage juice extract.....	5867	Piperazine wormer.....	5898
Cathomycin Calcium Syrup.....	5865	Pituitary, anterior, and orchic solution.....	5871
Compazine Spansule capsules...	5865	solution.....	5872
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Contour chairs.....	5892	Private Formula tablets.....	5861
Cosmetics (subject to the drug provisions of the Act).....	5882, 5884, 5888	Prophylactics, rubber.....	5880
Crisp Tonic Pills (veterinary)..	5863	Rectal thermometers.....	5879
Dentifrice, Vince.....	5870	Reducing devices.....	5890, 5891, 5893, 5894, 5897
Devices.....	5879, 5880, 5889-5897, 5900	Remanden-100.....	5865
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Dramcillin-250 tablets.....	5865	Rheumatism, remedies for.....	5886
Earache, remedy for.....	5881	devices for.....	5889, 5893, 5896
Electronic generator device....	5900	Scalp preparation. <i>See</i> Hair and scalp preparation.	
Elma Health Tea.....	5885	Sciatica, remedies for. <i>See</i> Rheumatism, remedies for.	
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Figure Trim Contour Pads.....	5893	Skin disorders, remedies for. 5884, 5886	
Gall bladder disorders, remedy for.....	5885	Slenda-Matic devices.....	5897
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Gout, remedies for. <i>See</i> Rheu- matism, remedies for.		Super Rybutol gelucaps.....	5876
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Hairnow Herbal Hair Tonic.....	5888	Tetrabon V Tetracycline Syrup..	5865
Handy-Hannah massager.....	5894	Thermometers, rectal.....	5879
I.O.D. powder (veterinary).....	5874	Thyroid tablets.....	5875
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Kidney disorders, remedy for...	5885	Trench mouth, remedy for.....	5870
Lumbago, remedies for. <i>See</i> Rheumatism, remedies for.		Ulcers, gastric, remedies for. 5867, 5883	

<sup>1</sup> (5869) Prosecution contested.

	N.J. No.		N.J. No.
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Veterinary preparations_____	5863,	cushion_____	5889
5873, 5874, 5898, 5899		pillows_____	5890
device_____	5900	Vimulator device_____	5895
Vi-Arthra capsules_____	5868	Vince Dentifrice_____	5870
		Vitamin preparations_____	5876

## SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

	N.J. No.		N.J. No.
A-1 Harmony Health Foods and Juices. <i>See</i> Shanklin, L. C.		Daylin Drugs, Inc.:	
Active Therapy Products Co.:		anterior pituitary solution_____	5872
Hairnow Herbal Hair Tonic_____	5888	Dean & Lee:	
Adelphi Surgical Co., Inc.:		medicated feed_____	5873
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Arman Drug Co., Inc.:		rubber prophylactics_____	5880
Arman's ear drops_____	5881	Delmar Pharmacal Corp.:	
As You Were Associates:		Dex-All capsules_____	5877
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Barnes-Hind Ophthalmic Products, Inc.:		antiseptic nasal spray_____	5864
Barnes-Hind Wetting Solution_____	5862	Grayline Co.:	
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Bel-Air Distributors:		Handy-Hannah massager_____	5894
Bel-Air vibrating lounge_____	5891	Hartel, Inc.:	
Bergman Drug Mfg. Co.:		Meducrin cream and Meducrin lotion_____	5882
Bergman's mixture_____	5883	Haver-Glover Laboratories:	
Bobrich Products Corp.:		Iocine_____	5899
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Bullock Vimulator Co.:		Iocine_____	5899
Vimulator device_____	5895	Health Appliances Corp.:	
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rectal thermometers_____	5879	Mi-Con Laboratories:	
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contour chairs_____	5892	P-M Laboratories, Inc.:	
Contour Lounge Shop. <i>See</i> Carney, J. C.		Teen-Clear_____	5884
Crisp, S. A., Canine Co.:		Peters Serum Co.:	
Crisp Tonic Pills (veterinary)_	5863	I.O.D. powder (veterinary)---	5874
		Po-Gi Enterprises:	
		sulfur bath concentrate_____	5886

	N.J. No.		N.J. No.
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taine anhydrous-----	5866, 5868	Strong, Cobb & Co., Inc.:	
Purity Drug Co.:		antiseptic nasal spray-----	5864
Crisp Tonic Pills (veterinary) _	5863	Theresa Pharmacy:	
Research Laboratories, Inc.:		various drugs-----	5865
I.O.D. powder (veterinary) ---	5874	United Contact Lens Corp.:	
Ripet Products Co., Inc.:		contact lens wetting solution--	5878
Elma Health Tea-----	5885	Vibra Mfg. Corp.:	
Rolender, S. S., Inc.:		vibrating cushion-----	5889
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San Joy Mfg. Co.:		cabbage juice extract-----	5867
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Shanklin, L. C.:		anterior pituitary and orchic	
aloe leaves and Papaya Rica-- <sup>1</sup>	5869	solution-----	5871
		anterior pituitary solution----	5872

<sup>1</sup> (5869) Prosecution contested.



**S A M P L E   C O P Y**

The Federal Register publishes the full text of Presidential Proclamations and Executive Orders, and the rules and regulations of the various Departments of the Federal Government.

## U.S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION  
U. S. DEPARTMENT OF AGRICULTURENOTICES OF JUDGMENT UNDER THE FEDERAL FOOD,  
DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

5901-5940

## DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts. One of the cases was instituted against the Government and the remainder of the cases were instituted by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were adulterated or misbranded within the meaning of the Act when introduced into and while in interstate commerce or while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings in which decrees of condemnation were entered after default or consent; (2) criminal proceedings terminated by pleas of guilty; (3) an injunction proceeding terminated by entry of a permanent injunction; and (4) a contempt proceeding for violation of a injunction which was terminated by a judgment of guilty. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation, and the criminal, contempt, and one of the injunction proceedings are against the *firms* or *individuals* charged to be responsible for violations, and the other injunction proceeding is against the Government.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs*.

WASHINGTON, D.C., August 11, 1960.

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\*For omission of, or unsatisfactory, ingredients statements, see Nos. 5905, 5908; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 5907, 5940; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, No. 5907.

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS  
REPORTED IN D.D.N.J. 5901-5940

*Adulteration*, Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength differed from, or its quality fell below, that which it purported or was represented to possess.

*Misbranding*, Section 502(a), the labeling of the article was false and misleading; Section 502(b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; Section 502(e) (2), the article was a drug not designated solely by a name recognized in an official compendium, and it was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient; Section 502(f), the labeling of the article failed to bear (1) adequate directions for use and (2) adequate warnings against use in those pathological conditions where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users.

*New-drug violation*, Section 505(a), the article was a new drug within the meaning of Section 201(p), which was introduced into interstate commerce, and an application filed pursuant to Section 505(b) was not effective with respect to such drug.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

5901. *Clarimycin*. Suit for injunction.

COMPLAINT FILED: On or about 2-10-58, Merritt Corp., Jersey City, N.J., filed a complaint for injunction in the United States District Court for the District of Columbia, against Marion B. Folsom, the Secretary of the Department of Health, Education, and Welfare, George P. Larrick, the Commissioner of the Food and Drug Administration, and William P. Rogers, the Attorney General of the United States.

NATURE OF CHARGE: The complaint alleged that Merritt Corp., plaintiff, was engaged in the distribution and sale of drug and cosmetic products, including "*Clarimycin*," an antibiotic lotion used in the treatment of acne pimples, which contained the active ingredient neomycin sulfate; that plaintiff had expended large sums of money on the product "*Clarimycin*"; that the defendants had, on 1-7-58 and 1-22-58, commenced libel actions against "*Clarimycin*" in the S. Dist. of Ohio, and the E. Dist. of Mich., respectively, by the seizure of plaintiff's product then being held for sale by retail customers of plaintiff; that such actions involve the same product, and the same issues, and that the defendant had interposed answers to the libel actions; that the issue in both libel actions involved a technical construction of Section 505, which, since its enactment, had not been subject to the review of the courts.

The complaint alleged further that the Government had already committed multiple seizures of plaintiff's product, and, that unless further seizures were enjoined, plaintiff would suffer irreparable harm and damage to its good will, reputation, and business; and that plaintiff would be deprived of its property without due process of law.

PRAYER FOR RELIEF: That a permanent injunction be issued restraining and enjoining defendants from instituting further proceedings, seizures, or condemnations against plaintiff's product "*Clarimycin*" under Section 304 of the Federal Food, Drug, and Cosmetic Act, pending determination of the libel



proceedings instituted by the defendants against "*Clarimycin*" in the S. Dist. of Ohio, and the E. Dist. of Mich.

**DISPOSITION:** The Government filed motions (1) for dismissal of the complaint on the ground that the complaint failed to state a claim on which relief could be granted, and (2) for the entry of a summary judgment, for the reason that the complaint and the affidavits of the plaintiff and the defendants showed that there was no genuine issue as to any material fact, and that defendants were entitled to judgment of dismissal as a matter of law.

On 5-5-58, the matter came on for hearing before the court, and thereafter, on 5-21-58, the court filed the following findings of fact and conclusions of law:

CURRAN, *District Judge:*

#### FINDINGS OF FACT

"1. On February 11, 1958, the plaintiff, Merritt Corp., filed a Complaint for Injunction seeking to restrain the defendant government officials from instituting further seizure actions against plaintiff's drug product, 'Clarimycin Anti-Biotic Acne Lotion.'

"2. Pursuant to Section 304 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 334] the defendants have caused to be instituted six seizure actions in various parts of the country against 'Clarimycin.' There was no Section 304 determination of probable cause.

"3. Each of the seizure actions instituted allege that 'Clarimycin' is a New Drug which may not be introduced into interstate commerce under the provisions of Section 505(a) [21 U.S.C. 355(a)], since an application filed pursuant to Section 505(b) [21 U.S.C. 355(b)] is not effective with respect to the drug.

"4. The active ingredient of 'Clarimycin' is the antibiotic neomycin sulfate.

"5. From 1949 to 1955 all neomycin sulfate preparations were deemed to be New Drugs requiring the filing of an application pursuant to Section 505 [21 U.S.C. 355] before the drug could be marketed in interstate commerce.

"6. In 1955 certain types of neomycin sulfate preparations were declared by the United States Food and Drug Administration no longer to be new drugs when labeled for use only for the prevention of infections in the temporary self-limiting conditions of minor cuts, burns and abrasions.

"7. Plaintiff markets its neomycin sulfate lotion preparation in interstate commerce for sale to the layman with labeling recommending use of the product for the treatment of acne.

"8. Acne vulgaris is a chronic, recurring disease condition of the skin which may last for years and which therefore requires treatment for a prolonged period of time.

"9. When viewed in the light most favorable to it, plaintiff's medical affidavits assert that topical neomycin sulfate is generally recognized by experts as safe in the treatment of acne, even when used over prolonged periods of time.

"10. Defendant's medical affidavits assert that topical neomycin sulfate is not generally recognized as safe by experts in the treatment of acne, because it has been shown to produce sensitization and cross-sensitization to streptomycin, an antibiotic valuable in the treatment of serious disease conditions. In addition, that use of neomycin sulfate for the treatment of acne is a new use for neomycin sulfate both because it has not been generally used for such a disease before and also because prolonged administration, which is required in an acne treatment, is a new method of utilizing the drug.

#### CONCLUSIONS OF LAW

"1. The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 334, imposes no limitations upon the number of seizure actions which may be instituted under a 'New Drug' charge, i.e. that the drug is one which may not, under the provisions of Section 505 [21 U.S.C. 355] be introduced into interstate commerce.

"2. Multiple seizures based on a 'New Drug' charge may be instituted without the making of any probable cause determination under Section 304 [21 U.S.C. 334].

"3. The newness of a drug, within the meaning of the Federal Food, Drug, and Cosmetic Act may arise by reason of, among others, a new or different recommended use for the drug, or a new or different duration of administration, even though the same drug may not be a new drug when used in another disease or other duration of administration.

"4. From the affidavits submitted it appears that a difference of medical opinion exists among the experts on whether topical neomycin sulfate is generally recognized as safe for the treatment of acne.

"5. Where there is a genuine difference of medical opinion among the experts on the question of whether a drug is generally recognized as safe for the treatment of a particular disease, it must be concluded that the drug is not *generally* recognized as safe for use in the treatment of that disease.

"6. It cannot be said therefore, that the defendant government officials have acted unreasonably or arbitrarily. The medical affidavits submitted by the defendants leaves no doubt as to the good faith of the officials.

"7. The institution of lawsuits alleging violation of the Federal Food, Drug, and Cosmetic Act is a matter of discretion vested in the defendant officials.

"8. Where discretion is vested in a government official and he acts in good faith in the light of the facts he ascertains and the judgment he forms, a Court cannot restrain him from acting, on the ground that he has exceeded his jurisdiction, even if his conclusion might have been induced by an error of fact or law.

"9. The defendant officials here were properly exercising the powers of the sovereign and the Court may not enjoin that action.

"10. The Court is without jurisdiction to enjoin the defendants.

"11. Plaintiff's motion for a Temporary Injunction will be denied.

"12. There exists no genuine issue as to any material fact and defendants are entitled to judgment as a matter of law on their motion to dismiss and for summary judgment.

"13. Defendant's motion to dismiss and for summary judgment will be granted.

"Let judgment be entered accordingly."

On the same day the court ordered that the plaintiff's motion for a preliminary injunction be denied, and further ordered that defendant's motion for summary judgment to dismiss the complaint be granted.

5902. Pega Palo vine. (F.D.C. No. 40293. S. No. 72-967 M.)

QUANTITY: 405 pliofilm pkgs. at Bountiful, Utah, in possession of B & M Distributing Co.

SHIPPED: 2-21-57, from Chicago, Ill., by A-1 Import Co.

LABEL IN PART: "Pega Palo."

ACCOMPANYING LABELING: Reprints entitled "Pega Palo The Vine That Makes You Virile" and leaflets entitled "Péga Palo Fact Sheet."

RESULTS OF INVESTIGATION: Some of the reprints and all of the leaflets were printed locally for the dealer.

LIBELED: 5-31-57, Dist. Utah.

CHARGE: 502(f) (1)—when shipped and while held for sale, the labeling of the article failed to bear adequate directions for its use as an aphrodisiac and as a sex rejuvenator which were the purposes for which the drug was intended; and 505(a)—the article was a new drug within the meaning of the law and an application filed pursuant to the law was not effective with respect to the drug.

DISPOSITION: 10-21-57. Default—destruction.

**DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS\*****5903. Herbal drugs. (Inj. No. 303.)**

COMPLAINT FOR INJUNCTION FILED: 10-11-56, W. Dist. Wash., against Forward Club, a corporation, Seattle, Wash., James L. Evans, president of the corporation, and Otto Soles, vice president of the corporation and also doing business as Keystone Laboratories, Portland, Oreg.

CHARGE: The complaint alleged that the defendants were causing and had caused to be introduced into interstate commerce at Seattle, Wash., and Portland, Oreg., certain herbal drugs, among which were articles designated as *Keystone Blood and Kidney Remedy*, *Keystone Liniment*, *Keystone Salve*, *Keystone Hair Regenerator*, *Herbs For Health*, *Indian Herbs*, and *Nature's Fresh Herbs* and which contained the following plants or herbs among their ingredients: horsetail, peach kernel, prickly thistle, common nettle, Oregon grape (whole plant or root), devil's club (prickly plant), elderberry (whole plant or root), stinging nettle, wild mountain grape root, Indian berry root, and umbelliferous root; that the articles were accompanied by various items of labeling when the defendants caused the articles to be introduced into interstate commerce, and while the defendants held the articles for sale after shipment in interstate commerce; and that the articles were misbranded as follows:

502(a)—the accompanying labeling of the articles contained false and misleading representations and suggestions that the articles were effective in the cure, mitigation, treatment, and prevention of arthritis, baldness, blood ailments and diseases, cancer, colds, colon troubles and diseases, corns, dandruff, diabetes, diarrhea, dysentery, falling hair, fever, gallbladder troubles and diseases, hemorrhages, hemorrhoids, kidney ailments and diseases, liver troubles and diseases, lung troubles and diseases, menstrual disorders, neuralgia, pain, rheumatism, scalp disorders and ailments, skin diseases and ailments, stomach troubles and diseases, ulcers, urinary ailments and disorders, warts, worms, wounds, and that the articles were effective to guarantee restoration and maintenance of health to the user regardless of the ailment from which he suffered; and

502(f) (1)—the labeling of the articles failed to bear adequate directions for use in all of the disease conditions for which they were intended.

The complaint alleged further that the defendants were causing the above-mentioned labeling to accompany the articles while the articles were held for sale after shipment in interstate commerce, which act resulted in the articles being misbranded in the respects set forth above.

DISPOSITION: 10-11-56. The defendants having consented, the court entered a decree of permanent injunction enjoining the defendants and their officers, agents, servants, employees, and all other persons in active concert or participation with any of them, from directly or indirectly doing the following acts with respect to the herbal drugs designated in the complaint, any other drug whose ingredients include any variety of the ingredients described in the complaint, and any other drug intended for the purposes mentioned in the complaint:

(a) introducing into interstate commerce any such drug which is (1) offered for the cure, mitigation, or treatment of arthritis, baldness, blood ailments

\* See also No. 5902.



and diseases, cancer, colds, colon troubles and diseases, corns, dandruff, diabetes, diarrhea, dysentery, falling hair, fever, gallbladder troubles and diseases, hemorrhages, hemorrhoids, kidney ailments and diseases, liver troubles and diseases, lung troubles and diseases, menstrual disorders, neuralgia, pain, rheumatism, scalp disorders and ailments, skin diseases and ailments, stomach troubles and diseases, ulcers, urinary ailments and disorders, warts, worms, wounds; or (2) which is offered to restore, maintain, or improve the health of the user; or

(b) doing any act with respect to such drug while such drug is held for sale after shipment in interstate commerce, which results in said drug being offered for any of the conditions or purposes described in paragraph (a) above.

**5904. Keystone Blood and Kidney Remedy.** (Inj. No. 303.)

PETITION FILED: 12-10-56, W. Dist. Wash., against Otto Soles, Portland, Oreg., to show cause why he should not be punished for criminal contempt for violation of the permanent injunction which had been entered against him on 10-11-56 (see preceding notice of judgment No. 5903).

CHARGE: The petition alleged that the defendant, in violation of the injunction, on 11-28-56, caused to be delivered for introduction into interstate commerce, at Portland, Oreg., consigned to Terre Haute, Ind., and Dayton, Ohio, a number of bottles of a drug designated as *Keystone Blood and Kidney Remedy* and containing herbs and organic minerals; that the drug was accompanied by leaflets entitled "Keystone Laboratories - The Drug Trust has subsidized" and "Keystone Laboratories - Keystone Blood and Kidney Remedy"; and that the labeling of the drugs, consisting of the bottle labels and accompanying leaflets, offered the drug for the cure, mitigation, treatment, and prevention of blood ailments and diseases, cancer, lung troubles and diseases, menstrual disorders, pain, ulcers, urinary ailments and disorders, and worms, and to restore, maintain, and improve the health of the user; and that by reason of such deliveries the defendant was in criminal contempt of the injunction.

DISPOSITION: On 12-10-56, the order to show cause was issued. On 12-17-56, the defendant having stipulated to a judgment of contempt, the court imposed a 6 months jail sentence which was suspended and placed the defendant on probation for 3 years.

**5905. Dermaden.** (F.D.C. No. 42782. S. No. 42-410 P.)

QUANTITY: 2 display ctns., each containing 8 120-cc. btls., and 16 240-cc. btls., at Seattle, Wash.

SHIPPED: 9-22-58, from Portland, Oreg., by Consumer Drug Corp.

LABEL IN PART: (Btl.) "Dermaden \* \* \* A Penicillin-Like Skin Application \* \* \* Antibiotic-Anaesthetic-Fungicidal. Distributed by Consumer Drug Corporation, Portland, Oregon \* \* \* Contains .01% Diatrex (Disodium-ethylene-diamine-tetracetate), 1% Benzocaine, 1% Salicylic Acid, 1% Resorcin, 2% Methyl Salicylate, 0.5% Phenol, 0.02% Tyrothricin in special greaseless, non-staining, Ultra-Microscopic Base"; (display ctn.) "Dermaden—Fights Fiery Itching, Promotes Healing, Combats Infection \* \* \* Contains U-M-B A New Concept in "Sustained Action" Skin Medication \* \* \* in addition to its anti-septic content, the very base of Dermaden is anti-bacterial and absorbs toxins \* \* \* Product of Consumer Drug Corporation."

LIBELED: About 1-15-59, W. Dist. Wash.

**CHARGE:** 502(a)—when shipped, the labeling contained false and misleading representations that the article was an adequate and effective treatment for inflamed conditions and common skin disorders, including eczema, allergies, nervous itch, and fungus infections; that the action of the article was essentially similar to that of penicillin; and that it represented a new concept in sustained action skin medication; 502(e) (2)—the label failed to bear the common or usual name of each active ingredient since the labeling of the article represented that the ointment base was itself an active ingredient and the label did not disclose the identity of the ointment base or list its ingredients; and 502(f) (2)—the labeling failed to bear such adequate warnings against unsafe dosage or methods or duration of administration in such manner and form as are necessary for the protection of users since its labeling failed to bear a warning in essentially the following form: "Warning: Not for prolonged use. Do not apply to large areas of the body. If redness, irritation, or swelling of the skin develops or pain persists or increases, discontinue use and consult a physician. Do not use in the eyes."

**DISPOSITION:** 5-25-59. Default—destruction.

**5906. Electronic devices.** (F.D.C. No. 41510. S. Nos. 16-164/5 P, 16-168 P.)

**QUANTITY:** 2 labeled devices and 1 unlabeled device at Newport, Ky., in possession of J. Vincent Reed, D.C.

**SHIPPED:** About 1939, 1943, and 1946, by Electronic Instrument Co., from Tiffin, Ohio.

**LABEL IN PART:** (On device) "Radioclast Model 40 Mfd. by Electronic Instrument Co., Tiffin, Ohio," (name plate) "Radioclast Mfd. by J. G. Miller, Tiffin, Ohio for the Electronic Instrument Co. Distributors Tiffin, Ohio Model 40 Serial 72," and (name plate) "Radioclast Mfd. by Electronic Instrument Company Tiffin, Ohio Model P."

**ACCOMPANYING LABELING:** Leaflets entitled "Electronic Laboratory Analysis Rates: Numerically Arranged" and "Electronic Analysis," shipped during March 1957, and on 1-14-58, by Electronic Instrument Co., Tiffin, Ohio.

**RESULTS OF INVESTIGATION:** Examination showed that the *Radioclast Model 40* consisted of a console desk-type instrument. The electronic elements of the instrument included a series of variable resistors, a group of coils, a power supply, an amplifier or oscillator unit, and a bakelite plate indicator. The panel contained 24 control knobs, 2 meters, a timer, and 9 plug-in connections.

The *Radioclast Model P* was similar to the above-described Model 40 but was smaller and was portable. The panel contained 11 control knobs, two switches, electrode connections, and a bakelite plate indicator.

The unlabeled unit was an electronic-magnetic treating unit. The panel contained 6 control knobs, a meter, and 4 electrode connections. Two sets of electrodes were used: (1) The electronic electrodes, which were to furnish a low-voltage, low-frequency current to the body; and (2) the magnetic electrodes which were to set up a magnetic field in the body between the electrodes. The bottom of the unit was a storage drawer.

**LIBELED:** 4-11-58, E. Dist. Ky.; libel amended 6-6-58.

**CHARGE:** 502(a)—when shipped and while held for sale, the labeling accompanying the devices contained false and misleading representations that the devices were capable of diagnosing or treating disease conditions of the brain, tonsils, prostate, spinal cord, trachea, lungs, kidneys, stomach, heart, liver, bones, eyes, and numerous other disease conditions; and 502(f) (1)—while held

for sale, the labeling of the devices failed to bear adequate directions for use for the purposes for which they were intended, namely, for diagnosing or treating leg trouble, menopausal difficulties, arthritis, poisons in the body, underactive or overactive organs, and fractures, which were the conditions for which they were orally represented by J. Vincent Reed, D.C., on 2-5-58.

**DISPOSITION:** On 5-19-58, J. Vincent Reed, D.C., claimant, filed an answer denying that the devices were misbranded as alleged in the libel, and on the same day filed a motion to dismiss the libel. The motion to dismiss was overruled on 6-24-58.

On 11-5-58, the Government filed written interrogatories which were served against the claimant. Subsequently, the Government filed a motion for order of default decree of condemnation for failure to answer the interrogatories. On 12-15-58, the claimant filed a second motion to dismiss the libel. The court, on 12-16-58, denied claimant's motion and denied also the Government's motion for default decree. The Government then filed a motion for order compelling an answer by the claimant to the written interrogatories. The court granted the motion on 12-30-58.

Thereafter, the Government and claimant having stipulated on additional facts, and having submitted the matter to the court for decision, the court, on 5-15-59, handed down findings of fact and conclusions of law to the effect that the leaflets accompanied and served to misbrand the devices. The court made no finding of misbranding under 502(f) (1).

On 5-21-59, judgment of condemnation was entered and the court ordered the devices to be delivered to the Food and Drug Administration.

#### DRUGS FOR VETERINARY USE

**5907. Medicated feed.** (F.D.C. No. 42903. S. No. 48-142 P.)

**QUANTITY:** 18 100-lb. bags at West Bridgewater, Mass.

**SHIPPED:** 2-13-59, by Dean & Lee, from Horseheads, N.Y.

**RESULTS OF INVESTIGATION:** The article was shipped in response to an order for a poultry feed containing 0.0125 percent sulfaquinoxaline.

Examination showed that the article delivered contained about 0.095 percent sulfaquinoxaline.

**LIBELED:** 3-25-59, Dist. Mass.

**CHARGE:** 501(c)—when shipped, the strength of the article differed from that which it purported to possess; 502(b)—the label of the article failed to bear (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; 502(e) (2)—the label failed to bear the common or usual name of each active ingredient; 502(f)—the labeling failed to bear (1) adequate directions for use and (2) adequate warnings against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of the user.

**DISPOSITION:** 5-4-59. Default—destruction.

**5908. Hexadin, Arsan Powder, and Weatol.** (F.D.C. No. 42927. S. Nos. 22-121/3 P.)

**QUANTITY:** 6 cases, 12 1-lb. jars each, and 4 25-lb. drums, of *Hexadin*, 10 8-oz. jars of *Arsan Powder*, and 2 1-gal. jars of *Weatol*, at Superior, Nebr.



**SHIPPED:** Between 4-14-58 and 10-10-58, from Kansas City, Kans., by Curts Laboratories.

**LABEL IN PART:** (Jar and drum) "Curts Hexadin with Dextrose 50% For oral administration in iodine deficiencies and in cases of actinomycosis in soft tissues that do not require surgery. Organic iodine compound . . . 5% (Hexamethylenetetramine tetraiodide 75.5% iodine) \* \* \* Directions \* \* \* Cattle and Horses \* \* \* Sheep and Swine."; (jar) "Curts Arsan Powder for swine dysentery or enteritis and/or a stomachic Sodium arsanilate . . . 26% \* \* \* Sodium phenolsulfonate, Iron pyrophosphate, Copper sulfate, Boric acid, Cobalt sulfate"; and (jar) "Curts Weatol Fish liver oil with alpha tocopherol acetate For oral administration as supplement in deficiencies of vitamins A, D and E. Daily dose Large animals \* \* \* Small animals."

**ACCOMPANYING LABELING:** Catalog entitled "Curts 1958 Products and Prices" and pamphlet entitled "Feature Drug Items Produced by Curts."

**LIBELED:** 4-9-59, Dist. Nebr.

**CHARGE:** 502(a)—(*Hexadin*) when shipped, the labeling, namely, the above-described catalog and pamphlet accompanying the article, contained false and misleading representations that the article was an adequate and effective treatment for the prevention of necrotic stomatitis and pneumonia, liver abscesses, calf diphtheria, keratitis, sterility and actinobacillosis in cattle, horses, sheep, and swine; (*Weatol*) the labeling, namely, the jar label and the above-described catalog and pamphlet accompanying the article, contained false and misleading representations that the article was an adequate and effective treatment for overcoming incidence of stillbirth and deformed offspring, and for increasing fertility of large and small animals; and the labeling of the *Weatol* also was misleading since it failed to reveal the amounts of vitamins A, D, and E present in the article, and also since the name "*Weatol*" suggested that the article contained a wheat germ oil base, when, in fact, it was labeled elsewhere as a fish liver oil base; and 502(f) (2)—(*Arsan Powder*) the article contained sodium arsanilate, and its labeling failed to warn that administration of the drug should be discontinued five days before slaughtering for human consumption to allow for elimination of the drug from the edible tissue.

**DISPOSITION:** 4-30-59. Default—destruction.

## DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS\*

**5909. Desarin tablets.** (F.D.C. No. 40575. S. Nos. 72-987/8 M.)

**QUANTITY:** 128 100-tablet btls. and 26 100-tablet btls. at Salt Lake City, Utah.

**SHIPPED:** 12-31-56 and 5-29-57, from St. Louis, Mo., by Victor M. Hermelin & Co.

**LABEL IN PART:** (128-tablet lot) "Desarin \* \* \* Estrogenic Substance \* \* \* Each tablet contains .625 mg. of estrogens in their naturally occurring water-soluble conjugated form \* \* \* Control No. 11-66"; or (26-tablet lot) "Each tablet contains 1.25 mg. of estrogens in their naturally occurring water-soluble conjugated form \* \* \* Control No. 5-66."

**RESULTS OF INVESTIGATION:** Analysis showed that the 128-tablet lot of the article contained 0.29 mg. of sodium estrone sulfate per tablet; and the 26-tablet lot of the article contained .91 mg. of sodium estrone sulfate per tablet.

\*See also No. 5907.

**LIBELED:** 9-13-57, Dist. Utah.

**CHARGE:** 501(c)—when shipped, the strength of the article differed from that which it purported and was represented to possess; and 502(a)—the label statements "Each tablet contains .625 mg. [or 1.25 mg.] of estrogens in their naturally occurring water-soluble conjugated form" were false and misleading.

**DISPOSITION:** 12-27-57. Default—destruction.

**5910. Conjugated estrogen tablets.** (F.D.C. No. 42755. S. No. 28-470 P.)

**QUANTITY:** 1 drum containing 20,000 tablets at Houston, Tex.

**SHIPPED:** 11-25-58, from Philadelphia, Pa., by Lustgarten Laboratories, Inc.

**RESULTS OF INVESTIGATION:** Analysis showed that the total estrogen content per tablet corresponded to not more than 0.70 milligram of sodium estrone sulfate.

**LIBELED:** 12-31-58, S. Dist. Tex.

**CHARGE:** 501(c)—when shipped, the strength of the article differed from that which it purported and was represented to possess, namely, that each tablet contained an amount of estrogens equivalent to 1.25 milligrams of sodium estrone sulfate; and 502(a)—when shipped and while held for sale, the label statement "Conjugated Estrogens 1.25 Mgm. \* \* \* expressed in terms of an equivalent quantity of Sodium Estrone Sulfate" was false and misleading.

**DISPOSITION:** 2-20-59. Default—destruction.

**5911. Dexobese timed disintegration capsules.** (F.D.C. No. 42781. S. No. 34-900 P.)

**QUANTITY:** 9 500-capsule btl., 24 100-capsule btl., and 71 30-capsule btl. at Philadelphia, Pa.

**SHIPPED:** 10-10-58, from Rensselaer, N.Y., by Delmar Pharmacal Corp.

**RESULTS OF INVESTIGATION:** The article was shipped in bulk as described above and after its receipt by the consignee at Philadelphia, Pa., was re-packaged in the above-mentioned bottles.

Analysis showed that the article contained 80.7 percent of the 15 mgs. of amphetamine sulfate per capsule which it was represented to have.

**LIBELED:** 1-9-59, E. Dist. Pa.

**CHARGE:** 501(c)—when shipped, the strength of the article differed from that which it purported and was represented to possess, since the article contained less than the declared amount of amphetamine sulfate.

**DISPOSITION:** 2-4-59. Default—destruction.

**5912. Para Dex Fifteen capsules and Para Barb 3 capsules.** (F.D.C. No. 42796. S. Nos. 41-592/3 P.)

**QUANTITY:** 57 100-capsule btl., and 11 250-capsule btl., of *Para Dex Fifteen capsules*, and 97 100-capsule btl., of *Para Barb 3 capsules*, at Salem, Oreg.

**SHIPPED:** 10-6-58, from Rensselaer, N.Y., by Delmar Pharmacal Corp.

**LABEL IN PART:** (Btl.) "Para Dex Fifteen Capsules Three Releases \* \* \* Each Para Dex Fifteen Capsule contains 15 mg. of Dextro-Amphetamine Sulfate to release uniformly over a period of six to ten hours," and "Para Barb 3 Capsules \* \* \* Each Para Barb 3 Capsule contains: Phenobarbital 100 mg. A brand of time disintegration capsule."

**RESULTS OF INVESTIGATION:** The articles were shipped in bulk as described above and upon receipt at Salem, Oreg., were repacked into the above-mentioned bottles and labeled as described above by the dealer.

Examination showed that 70 percent of the labeled amount of dextro-amphetamine in the *Para Dex Fifteen capsules* was released in a two-hour period; and that the *Para Barb 3 capsules* contained 75 percent of the labeled amount of phenobarbital.

**LIBELED:** 2-2-59, Dist. Oreg.

**CHARGE:** 501(c)—when shipped, the quality of the *Para Dex Fifteen capsules* fell below that which they were represented to possess since the dextro-amphetamine ingredient was not released at a uniform rate over a six- to ten-hour period, and the strength of the *Para Barb 3 capsules* differed from that which they were represented to possess since the article contained only 75 percent of the labeled amount of phenobarbital; and 502(a)—the label statements "Each Para Dex Fifteen Capsule contains 15 mg. of Dextro-Amphetamine Sulfate to release uniformly over a period of six to ten hours" and "Each Para Barb 3 Capsule contains: Phenobarbital 100 mg." were false and misleading.

**DISPOSITION:** 3-12-59. Default—destruction.

**5913. Martabs No. 2.** (F.D.C. No. 42830. S. No. 10-336 P.)

**QUANTITY:** 43 500-tablet btls. at Pittsburgh, Pa.

**SHIPPED:** 12-5-58 and 1-9-59, from Mansfield, Ohio, by Caldwell & Bloor Co.

**LABEL IN PART:** "Martabs No. 2 \* \* \* Distributed \* \* \* by The Caldwell and Bloor Co. Mansfield, Ohio. Each Tablet Contains: Phenobarbital \* \* \* 16 mg. Calcium Carbonate 0.5 gm. Magnesium Oxide 0.25 gm. Atropine Sulfate 0.2 mg."

**RESULTS OF INVESTIGATION:** Examination showed that the article contained between 56 and 82 percent of the labeled amount of phenobarbital.

**LIBELED:** 2-11-59, W. Dist. Pa.

**CHARGE:** 501(c)—when shipped, the strength of the article differed from that which it was represented to possess; and 502(a)—the label statement "Each Tablet Contains: Phenobarbital 16 mg." was false and misleading.

**DISPOSITION:** 4-17-59. Default—destruction.

**5914. Rubber prophylactics.** (F.D.C. No. 42975. S. No. 10-667 P.)

**QUANTITY:** 63 gross ctns., 12 pkgs. each, at Syracuse, N.Y.

**SHIPPED:** 9-19-58, from Akron, Ohio, by Killashun Sales Div. of the Akwell Corp.

**LABEL IN PART:** (Pkg.) "Xcello's prophylactics \* \* \* Mfg. by The Killian Mfg. Div. of the Akwell Corp. Akron, Ohio Contents One Dozen."

**RESULTS OF INVESTIGATION:** Examination showed that 1 percent contained holes.

**LIBELED.** 4-16-59, N. Dist. N.Y.

**CHARGE:** 501(c)—when shipped, the quality of the article fell below that which it purported to possess; and 502(a)—the label statement "Prophylactics \* \* \* Sold for Prevention of Disease Only" was false and misleading.

**DISPOSITION:** 5-26-59. Default—destruction.



**9515. Rubber prophylactics.** (F.D.C. No. 42920. S. Nos. 32-768 P, 32-770/3 P, 32-775 P.)

**QUANTITY:** 313 gross ctns., each containing 4 ctns. of 12 3-unit tins each, and 49 cases, each containing 50 gross, at New York, N.Y., in possession of Goodwear Rubber Co., Inc.

**SHIPPED:** Between 8-15-58 and 2-25-59, from Akron, Ohio, by Killashun Sales Div. of Akwell Corp.

**LABEL IN PART:** (Tin) "Three Knights \* \* \* 1/4 Doz. \* \* \* distributed by Goodwear Rubber Co." and "Chariots 1/4 Doz. \* \* \* distributed by Goodwear Rubber Co., New York, N.Y.," (ctn.) "Three Knights" or "AXNE Chariots Tubed Killian."

**RESULTS OF INVESTIGATION:** Examination showed that between 1.4 percent and 16 percent of the article contained holes. Inspection of the plant of the Goodwear Rubber Co. showed that the article in the 313-ctn. lot had been repacked from bulk stock shipped as described above and had been damaged in the course of the repacking operation.

**LIBELED:** 4-17-59, S. Dist. N.Y.

**CHARGE:** 501(c)—the quality of the 49-case lot, when shipped, and the quality of the 313-ctn. lot, while held for sale, fell below that which they purported and were represented to possess; and 502(a)—the label statements "Sold For Prevention of Disease Only" and "For Protection Against Disease" were false and misleading.

**DISPOSITION:** 5-13-59. Default—destruction.

**5916. Rubber prophylactics.** (F.D.C. No. 42730. S. Nos. 10-156 P.)

**QUANTITY:** 48 12-pkg. ctns., each pkg. containing 12 prophylactics, at Rochester, N.Y.

**SHIPPED:** 12-9-58 and 1-6-59, from New York, N.Y., by Goodwear Rubber Co.

**LABEL IN PART:** (Pkg.) "Texide Prophylactics \* \* \* Mfg. by L. E. Shunk Latex Prod. of the Akwell Corp. Akron, Ohio."

**RESULTS OF INVESTIGATION:** An examination of 150 units showed that 5.3 percent were defective in that they contained holes.

**LIBELED:** 3-6-59, W. Dist. N.Y.

**CHARGE:** 501(c)—when shipped, the quality of the article fell below that which it purported to possess; and 502(a)—the label statement "Prophylactics" was false and misleading as applied to an article containing holes.

**DISPOSITION:** 4-13-59. Default—destruction.

**5917. Rubber prophylactics.** (F.D.C. No. 42879. S. No. 50-790 P.)

**QUANTITY:** 3 bulk drums containing a total of 1,000 gross *rubber prophylactics* at Chicago, Ill.

**SHIPPED:** 2-18-59, from Carolina, Puerto Rico, by De Caribe Rubber Co.

**LABEL IN PART:** (Prophylactic) "Protex \* \* \* National Sanitary Sales."

**RESULTS OF INVESTIGATION:** Examination showed that 1.4 percent of the article contained holes.

**LIBELED:** 3-10-59, N. Dist. Ill.

**CHARGE:** 501(c)—when shipped, the quality of the article fell below that which it purported to possess; and 502(a)—the label statement "An aid for the prevention of venereal disease" was false and misleading.

**DISPOSITION:** 3-27-59. Consent—claimed by Dean Rubber Mfg. Co., Kansas City, Mo. 398 lbs. were reconditioned and 10 lbs. were segregated and destroyed.

**5918. Rubber prophylactics.** (F.D.C. No. 42842. S. No. 47-157 P.)

**QUANTITY:** 619 gross at Chicago, Ill., in possession of National Sanitary Sales, Inc.

**SHIPPED:** 9-12-58, from New Orleans, La., by De Caribe Rubber Co., Carolina, Puerto Rico.

**LABEL IN PART:** (Bulk stock) "Protex \* \* \* Product of National Sanitary Sales, Chicago 45, Ill.," (ctn.) "Protex \* \* \* Prophylactics \* \* \* Package of Two \* \* \* A Product of National Sanitary Sales, Inc., Chicago 45, Ill."

**RESULTS OF INVESTIGATION:** Examination showed that 1.6 percent of the article contained holes.

The portion of the article in cartons was repackaged by the dealer from bulk stock shipped as described above.

**LIBELED:** 2-16-59, N. Dist. Ill.

**CHARGE:** 501(c)—when shipped and while held for sale, the quality of the article fell below that which it purported to possess.

**DISPOSITION:** 3-11-59. Consent—claimed by Dean Rubber Mfg. Co., Kansas City, Mo. Segregated; 10 lbs. destroyed.

**5919. Clinical thermometers.** (F.D.C. No. 42839. S. No. 36-118 P.)

**QUANTITY:** 538 thermometers at Philadelphia, Pa.

**SHIPPED:** 12-23-58, from New York, N.Y., by Chase Mfg. Co.

**LABEL IN PART:** (Envelope) "Clinical Thermometer tested and certified to comply with CS 1-52 Stubby Oral."

**LIBELED:** 2-12-59, E. Dist. Pa.

**CHARGE:** 501(c)—when shipped, the quality of the article fell below that which it was purported and represented to possess since it did not give accurate readings; and 502(a)—the label statement "tested and certified to comply with CS 1-52" was false and misleading.

**DISPOSITION:** 3-25-59. Consent—claimed by Chase Mfg. Co. Segregated; 221 thermometers destroyed.

#### DRUGS FOR VETERINARY USE

**5920. Stockade procaine penicillin.** (F.D.C. No. 42302. S. No. 26-482 P.)

**QUANTITY:** 20 10-lb. bags at Des Moines, Iowa.

**SHIPPED:** 7-15-58, from Pittsburg, Kans., by Harvest Brand, Inc.

**LIBELED:** 11-14-58, S. Dist. Iowa.

**CHARGE:** 501(c)—the strength of the article, when shipped and while held for sale, differed from that which it purported and was represented to possess since its label claimed that the article contained .7938 grams of procaine penicillin (equivalent to .445 grams of crystalline penicillin) per pound, whereas the article contained a significantly lesser amount of penicillin potency; and 502(a)—the label statement "Active Drug Ingredient: .7938 gms. or 793,800 units of Procaine Penicillin per pound. (Equivalent to .445 gms. crystalline penicillin G Master Standard)" was false and misleading.

**DISPOSITION:** 12-24-58. Default—destruction.

**5921. Medicated feed.** (F.D.C. No. 42751. S. No. 47-553 P.)

QUANTITY: 28 100-lb. bags at Methuen, Mass.

SHIPPED: 9-13-58 and 10-7-58, from Horseheads, N.Y., by Dean & Lee.

LABEL IN PART: "Pathfinder Medicated Jumbo Starter-Broiler \* \* \* Active drug ingredients: Nicarbazin 0.0125% \* \* \* Crude Fat (minimum) 7.00% \* \* \* Manufactured by Dean & Lee, Horseheads, N.Y."

RESULTS OF INVESTIGATION: Examination showed that the article contained little or no Nicarbazin and was deficient in fat content.

LIBELED: 12-29-58, Dist. Mass.

CHARGE: 501(c)—when shipped, the strength of the article differed from and its quality fell below that which it purported or was represented to possess; and 502(a)—the label statement "Nicarbazin 0.0125% \* \* \* Crude Fat 7.00%" was false and misleading.

DISPOSITION: 3-30-59. Default—destruction.

### DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

#### DRUGS FOR HUMAN USE\*

**5922. First Aid for Headache.** (F.D.C. No. 42809. S. No. 47-510 P.)

QUANTITY: 22 ctns, each containing 12 vials, at Somerset, Mass.

SHIPPED: 10-28-58, from Philadelphia, Pa., by Chex Co.

LABEL IN PART: (Vial) "1st Aid for Headache \* \* \* Active ingredients: Acetophenetidin  $2\frac{1}{2}$  grains, Salicylamide, Aluminum Hydroxide, Magnesium Hydroxide, Caffeine. Made by Aitchison Laboratories, Phila. Pa."

LIBELED: 1-28-59, Dist. Mass.

CHARGE: 502(a)—when shipped, the label contained false and misleading representations that the article was an adequate and effective treatment for all those symptoms commonly associated with nervousness and the conditions known as "hangover."

DISPOSITION: 4-9-59. Consent—destruction.

**5923. Mineral water.** (F.D.C. No. 41952. S. No. 14-904 P.)

QUANTITY: 3,188 btls. at Cleveland, Ohio.

SHIPPED: 11-20-57, from Yugoslavia, by Mercator Ljubljana.

LABEL IN PART: "Radenska Natural Mineral Waters \* \* \* Analysis of the Radenska King Spring \* \* \* One litre of water contains: Cations: Potassium, 132, 1 mg.; Sodium, 1,051 mg.; Lithium, 1,35 mg.; Ammonium, 1,08 mg.; Calcium, 181,4 mg.; Strontium, 3,17 mg.; Magnesium, 76,2 mg.; Iron, 7,3 mg.; Manganese, 0,13 mg.; Aluminum, 0,48 mg.; Anions: Chlorine, 110,2 mg.; Bromine, 1,09 mg.; Iodine, 0,06 mg.; Nitrate, 1,52 mg.; Hydrophosphate, 0,66 mg.; Sulfate, 201,0 mg.; Hydrocarbonate, 3,521,0 mg.; Weak electrolytes: Silicic-acid, 32,0 mg.; Titanic-acid, 0,05 mg.; Boric-acid, 17,0 mg.; \* \* \* Free carbonic acid, 3,138,0 mg. \* \* \* Contents 1 quart 1 oz. Bottled for Tivoli Imports, 6407 St. Clair Avenue, Cleveland 3, Ohio, U.S.A."

ACCOMPANYING LABELING: Booklets entitled "Radenska Health Springs" and others printed in Slovene entitled "Radenska Slatina."

LIBELED: 8-5-58, N. Dist. Ohio.

\*See also Nos. 5903, 5905, 5906, 5909, 5912-5917, 5919.



CHARGE: 502(a)—when shipped and while held for sale, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for gout, sclerosis, kidney disease, articular inflammation, headache, bladder troubles, swelling of the prostate gland, kidney stones and gravel, inflammation of the kidney, gastric hyperacidity, gastric ulcer, colitis, ulcer of the bowels, gastric and intestinal catarrh, bad taste in the mouth, bellyache, enteritis, bilious attacks, gallstones, liver complaints, jaundice, decrepitude and bodily weakness, neurasthenia, nervousness, fainting, nervous debility, catarrhs of the bronchia or lungs, catarrh of the throat, difficult breathing, goiter hyperthyroidism, Basedow's disease, diabetes, rheumatism, pain in the joints, lumbago, contagious diseases, grippe, inflammation, impure blood, women's diseases, diseases of adolescence, scrofula, malfunctioning of the glands of the internal secretion, and for preventing bad effects due to excessive drinking and eating.

DISPOSITION: 4-29-59. Default—destruction.

**5924. Eucalyptus oil compound.** (F.D.C. No. 42884. S. No. 35-856 P.)

QUANTITY: 47 2-oz. btls., 31 8-oz. btls., and 27 4-oz. btls., at Philadelphia, Pa.

SHIPPED: 1-28-59, from Pitman, N.J., by Pitman Chemical Laboratories, Inc.

LABEL IN PART: "Mustiez Eucalyptus Oil Compound \* \* \* 100% U.S.P. or N.F. Oil Eucalyptus, Methyl Salicylate, Gum Camphor, Peppermint, Thymol, Menthol. \* \* \* Mustiez Products, Box 311, Trevese, Pa."

ACCOMPANYING LABELING: Leaflets entitled "Mustiez Eucalyptus Oil Compound."

LIBELED: 3-13-59, E. Dist. Pa.

CHARGE: 502(a)—when shipped, the labeling accompanying the article contained false and misleading representations that the article was an adequate and effective treatment for arthritis, rheumatism, sciatica, bursitis, lumbago, sinusitis, and "irritation."

DISPOSITION: 4-15-59. Default—destruction.

**5925. Amphetamine tablets.** (F.D.C. No. 42952. S. No. 15-647 P.)

QUANTITY: 24 btls. at Dayton, Ohio.

SHIPPED: 9-20-58, from Philadelphia, Pa., by J. W. S. Delavau Co., Inc.

LABEL IN PART: "Four Amphetamines 2.5 Mg. each tablet contains: Phenobarbital  $\frac{1}{4}$  gr. \* \* \* Racemic Amphetamine 2.5 Mg. Dextroamphetamine 2.5 Mg. Methamphetamine 2.5 Mg. Methamphetamine Pot. Saccharate 2.5 Mg. \* \* \* Manufactured for Halsom Drug Co., Dayton, Ohio."

RESULTS OF INVESTIGATION: Analysis showed that the article contained 62 percent of the labeled amount of total amphetamines and 28 percent of the labeled amount of phenobarbital.

LIBELED: 3-26-59, S. Dist. Ohio.

CHARGE: 502(a)—when shipped, the label statement "Each tablet contains: Phenobarbital  $\frac{1}{4}$  gr. \* \* \* Racemic Amphetamine 2.5 Mg. Dextroamphetamine 2.5 Mg. Methamphetamine 2.5 Mg. Methamphetamine Pot. Saccharate 2.5 Mg." was false and misleading.

DISPOSITION: 4-22-59. Default—destruction.

**5926. Groff's Artha-Tone.** (F.D.C. No. 42312. S. No. 41-293 P.)

QUANTITY: 29 50-tablet btls., 42 100-tablet btls., and 9 250-tablet btls., at Tacoma, Wash.

SHIPPED: Between 9-16-58 and 10-6-58, from Portland, Oreg., by Glenn Matteson Co., Inc.

LABEL IN PART: "Groff's Artha-Tone \* \* \* Each Tablet contains Rose Hips Natural Vitimin C 30 Mg. \* \* \* Natural Organic Salicylate (Natural Oil of Wintergreen) in a base containing powdered Alfalfa Seed, Dried Alfalfa Juice concentrate, Twin Root and powdered Celery Seed."

ACCOMPANYING LABELING: Leaflets entitled "Why Suffer Pain!"

LIBELED: 11-18-58, W. Dist. Wash.

CHARGE: 502(a)—the labeling of the article, when shipped, contained false and misleading representations that the article was an adequate and effective treatment for arthritis and rheumatism.

DISPOSITION: 4-8-59. Default—destruction.

5927. Royal jelly capsules. (F.D.C. No. 41705. S. No. 15-087 P.)

QUANTITY: 60,500 capsules at Shelbyville, Tenn.

SHIPPED: 3-29-58, from Long Island City, N.Y.

LABEL IN PART: (Vial) "30 Capsules Royal Queen Pure Royal Jelly Natural Food Supplement Each Capsule \* \* \* contains 50.0 Mgm. Royal Jelly \* \* \* Tennessee Royal Jelly Company \* \* \*"; (carton) "Royal Queen Capsules Pure Royal Jelly \* \* \*"; (carton insert) "Royal Jelly Message to Drug Stores, Hospitals, Wholesale Drug Companies, and Physicians."

ACCOMPANYING LABELING: Leaflets entitled "Royal Queen Brand Capsules Royal Jelly the Amazing Natural Super Food."

RESULTS OF INVESTIGATION: The article had been shipped in bulk drums and after receipt by the consignee were repacked into vials. The vials were packed into cartons. The leaflets were printed at Shelbyville, Tenn.

LIBELED: 5-19-58, E. Dist. Tenn.

CHARGE: 502(a)—the labeling accompanying the article contained false and misleading representations that it was an adequate and effective treatment for stimulating appetite, restoring muscular strength, strengthening debilitated nerves, activating all glands, combating disease, creating a feeling of well-being, increasing life span and increasing sex activity; and overcoming tiredness, irritability, headaches, insomnia, and physical and mental tensions.

DISPOSITION: 6-16-58. Consent—claimed by Tennessee Royal Jelly Co., Shelbyville, Tenn., and relabeled.

5928. Elixir Ebicol. (F.D.C. No. 42437. S. No. 30-091 P.)

INFORMATION FILED: 3-17-59, Dist. Conn., against Marvin R. Thompson, Inc., Stamford, Conn.

SHIPPED: 12-10-57, from Connecticut to New York.

LABEL IN PART: (Btl.) "ELIXIR EBICOL-MRT 8 Fluid Ounces 236 cc. MARVIN R. THOMPSON, INC. STAMFORD, CONN."

CHARGE: 502(a)—when shipped, the label statement "Each teaspoonful (5 cc.) contains: Thiamine Hydrochloride (Vitamin B<sub>1</sub>) 1 mg." was false and misleading since the article contained less than 1 milligram of thiamine hydrochloride (vitamin B<sub>1</sub>).

PLEA: Guilty.

DISPOSITION: 4-27-59. Fine of \$100 and costs.

**5929. Dr. Navaun's Tablets.** (F.D.C. No. 42246. S. No. 11-364 P.)

QUANTITY: 60,000 tablets in bulk drums and 216 unlabeled btl. at Lapeer, Mich., in possession of Botanic Drug Co.

SHIPPED: 8-1-56, from Philadelphia, Pa.

LABEL IN PART: (Btl.) "Dr. Navaun's Tablets \* \* \* Contain: Ext. Elder Flowers, Shepherd's Purse, Hydrangea, Juniper Berries, Methylene Blue, Pot. Nitras, Podophyllum Resin."

ACCOMPANYING LABELING: Booklets entitled "Dr. Navaun's Tablets."

RESULTS OF INVESTIGATION: A portion of the bulk stock was repacked into the bottles which were to be labeled as described above.

LIBELED: 10-24-58, E. Dist. Mich.

CHARGE: 502(a)—while held for sale, the labeling contained false and misleading representations that the article was a mild diuretic and stimulant to the kidneys.

DISPOSITION: 3-17-59. Default—destruction.

**5930. Lecithin tablets.** (F.D.C. No. 41569. S. No. 16-595 P.)

QUANTITY: 2 90-tablet btl., 10 180-tablet btl., and 9 540-tablet btl., at Cincinnati, Ohio.

SHIPPED: 2-27-58 and 5-1-58, from Chicago, Ill., by Health Food Jobbers, Inc.

LABEL IN PART: (Btl.) "National Lecitabs Lecithin Tablets A Natural Food Product \* \* \* Ingredients: Soya Lecithin, in a base of non-fat, dry milk solids and soy protein. Natural flavoring added. Distributed by National Lecithin, Inc. \* \* \* Chicago 14, Ill."

ACCOMPANYING LABELING: Circulars entitled "Amazing New Lecithin Discovery."

LIBELED: 5-21-58, S. Dist. Ohio.

CHARGE: 502(a)—when shipped, the labeling which accompanied the article contained false and misleading representations that the article was an adequate and effective treatment for heart conditions, arthritis, rheumatism, and other rheumatic-like disorders.

DISPOSITION: 3-9-59. Default—destruction.

**5931. Botab tablets and Diuretic Liquid.** (F.D.C. No. 42570. S. Nos. 908/9 P.)

QUANTITY: 248 100-tablet btl. of Botab, and 1 btl. *Diuretic Liquid*, at Tifton, Ga., in possession of George A. Wright, Inc.

SHIPPED: (*Botab tablets*) 8-20-58, and (*Diuretic Liquid*) between February and October, 1958, from Chicago, Ill.

LABEL IN PART: (Btl.) "Botab \* \* \* Active ingredients: Magnesium oxide, Soda bicarbonate, Bismuth subnitrate. Distributed by The Botab Company, Tifton, Georgia" and "R-X Diuretic Liquid A mildly stimulating alkaline diuretic \* \* \* Active Ingredients: F. E. Buchu, Saw Palmetto, Triticum and Hyoscyamus (each tablespoonful contains 1/2500 grain Alkaloid of Hyoscyamus) with Potassium Bicarbonate and Lithum Benzoate \* \* \* Directions \* \* \* Distributed by The Botab Company, Tifton, Ga."

ACCOMPANYING LABELING: Circulars entitled "Clogged Kidneys Can Cause Backache, Tiredness," "Why Suffer Any Longer . . . Act Now," and "Eat Less . . . Lose Weight . . . Live Longer . . . Feel Better."



RESULTS OF INVESTIGATION: The dealer had attached the circulars to the articles with rubber bands.

LIBELED: 12-13-58, M. Dist. Ga.

CHARGE: 502(a)—While held for sale, the labeling which accompanied the articles contained false and misleading representations that the *Botab Tablets* were an adequate and effective treatment for stomach ulcers; and that the *Diuretic Liquid* was an adequate and effective treatment for all kidney conditions that cause backache, tiredness, dizziness, getting up nights, and poor appetite.

DISPOSITION: 3-27-59. Consent—claimed by George A. Wright, Inc. The *Botab tablets* were relabeled and the *Diuretic Liquid* was destroyed.

5932. Medicated plasters. (F.D.C. No. 42697. S. No. 10-345 P.) .

QUANTITY: 26 boxes, each containing 24 plasters, at Pittsburgh, Pa.

SHIPPED: 11-5-58, from Kattskill Bay, N.Y., by Raymond Pectoral Plaster Co., Inc.

LABEL IN PART: (Box) "Raymond's Pectoral Plaster \* \* \* Raymond Pectoral Plaster Co., Inc., Glens Falls, New York"; (plaster) "Raymond's Pectoral Plaster \* \* \* This Plaster is Four Days' treatment only, Each plaster contains: Olive And Cotton Seed Oils, Litharge, Gum Olibanum, Gumthus, Rosin, Rubber, Gilsonite, Niger Gutta Gum, Extract Made From The Herb Lobelia."

ACCOMPANYING LABELING: (Circular enclosed in box) "Raymond's Pectoral Plaster."

LIBELED: 2-13-59, W. Dist. Pa.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for relieving whooping cough, croup, coughs, spasmodic asthma, and hoarseness due to colds.

DISPOSITION: 4-17-59. Default—destruction.

5933. Relax-A-Pad device. (F.D.C. No. 42275. S. No. 41-958 P.)

QUANTITY: 9 individually cartoned devices at Everett, Wash.

SHIPPED: 10-22-58 and 10-29-58, from Los Angeles, Calif., by Relax-A-Cushion, Inc.

LABEL IN PART: (Ctn.) "Relax-A-Pad Health Unit Human Hand Action Cycloid Massage."

ACCOMPANYING LABELING: Leaflets entitled "Topper Relax-A-Pad 3-Way Systems Program."

RESULTS OF INVESTIGATION: The article consisted of a foam rubber upholstered cushion with a cylindrical attachment at one end containing a vibrator motor. The cushion contained a heating element and a separate control box which regulated the heat and vibration.

LIBELED: On or about 11-17-58, W. Dist. Wash.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that it was an adequate and effective treatment for rheumatism, bursitis, and arthritis; stimulating and promoting circulation; breaking down fatty tissues; relief of muscular aches and pains; relieving tension; and reducing weight without diet.

DISPOSITION: 4-24-59. Default—destruction.

**5934. Casco Thermal Massager.** (F.D.C. No. 42299. S. No. 19-806 P.)

QUANTITY: 45 individually cartoned devices at Oklahoma City, Okla.

SHIPPED: 9-10-58 and 9-30-58, from Bridgeport, Conn., by Casco Products Corp.

LABEL IN PART: (Tag on device) "Deluxe Automatic Thermal Massager," (label on switch) "Casco Thermal Massager."

ACCOMPANYING LABELING: Circulars entitled "A Wonderful New Way To Relax And Feel Better"; leaflet entitled "Authorized Service Stations" and "The Magic of Massage"; placards entitled "Casco Deluxe Thermal Massager."

RESULTS OF INVESTIGATION: The article was an upholstered semi-rigid cushion containing a heating element and motor capable of providing vibration.

LIBELED: 11-13-58, W. Dist. Okla.

CHARGE: 502(a)—the labeling which accompanied the article, when shipped, contained false and misleading representations that it was an adequate and effective treatment for arthritis, bursitis, lumbago, rheumatism, increasing blood circulation, overcoming accidental muscular strains and aches, reducing weight, relieving nervous tension, melting away pounds and inches, and for providing a "fountain of youth."

DISPOSITION: 3-13-59. Consent—claimed by Casco Products Corp., and relabeled.

**5935. Slim-Trim Lounge.** (F.D.C. No. 42727. S. No. 46-031 P.)

QUANTITY: 5 devices, individually cartoned, at New Orleans, La.

SHIPPED: Between 11-14-58 and 12-3-58, from St. Louis, Mo., by Slim-Trim Mfg. Co.

LABEL IN PART: (Ctn.) "Slim-Trim Lounge, Slim-Trim Mfg. Co."

ACCOMPANYING LABELING: Leaflets in carton entitled "Slim-Trim Lounge"; other leaflets entitled "Manual For Selling Slim Trim Lounge" and "How To Use The Slim Trim Lounge."

RESULTS OF INVESTIGATION: The article consisted of a rectangular box-shaped housing containing an electric motor capable of providing a vibrating or oscillating motion to a padded cushion attached to the top of the housing. Padded tubular steel extensions could be attached to the housing to form a cot-like device.

LIBELED: 3-6-59, E. Dist. La.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for relieving and eliminating arthritis, rheumatism, and bursitis; eliminating muscular aches and pains; causing nervous tension to disappear; breaking down fatty tissue and increasing blood circulation to carry away waste fat; proving "The only easy way to reduce"; overcoming nagging tension headaches; slimming, trimming, and reducing the figure; relieving varicose veins, diabetes, high and low blood pressure; helping women through menopause, and correcting bone alignment.

DISPOSITION: 4-7-59. Consent—claimed by Michael A. Costa, t/a Slim Trim of Louisiana, New Orleans, La., and relabeled.

**5936. Health-O-Pedic Chairs.** (F.D.C. No. 42740. S. No. 10-049 P.)

QUANTITY: 20 devices at Buffalo, N.Y.

SHIPPED: 5-27-58, 5-29-58, and various other dates, from Fresno, Calif., by Health-O-Pedic Chair Co.

LABEL IN PART: (Chair) "Made especially for Health-O-Pedic Chair."

ACCOMPANYING LABELING: Leaflets entitled "The Health-O-Pedic Chair Company Invites You To A New Way Of Life."

RESULTS OF INVESTIGATION: The article consisted of an upholstered reclining chair, adjustable to several positions, and equipped with an electric motor capable of providing a vibrating or oscillating movement.

LIBELED: 3-11-59, W. Dist. N.Y.

CHARGE: 502(a)—the labeling of the article, when shipped, contained false and misleading representations that the article was an adequate and effective treatment for relieving nervous tension, bursitis, arthritis, rheumatism, headaches and backaches; providing deep penetrating massage; and for providing "a new way of life" and health insurance.

DISPOSITION: 4-30-59. Consent—claimed by Cladco Distributors, Inc., Buffalo, N.Y., and relabeled.

#### DRUGS FOR VETERINARY USE\*

5937. Algit Norwegian Kelp Meal. (F.D.C. No. 42896. S. No. 42-671 P.)

QUANTITY: 660 50-lb. bags at Spokane, Wash.

SHIPPED: 7-9-58 and 9-12-58, from Kristiansund N, Norway, by Algea Produkter A. S.

LABEL IN PART: "Algit the Norwegian Kelp Meal Product of Norway Guaranteed Analysis Crude Protein, not less than 5% Crude Fat, not less than 2% Crude Fibre, not more than 8% Salt (NaCl), not more than 3% Phosphorus (P), not less than 0.2% Iodine (I), not less than 0.06% Calcium (Ca), not less than 1.5% Ingredients . . . Norwegian Kelp Meal Usage: 2% of grain ration for animal feeding Algea Produkter A. S. Kristiansund N, Norway."

ACCOMPANYING LABELING: Leaflets entitled "The Sunday Star Magazine Farming Without Fertilizer," "Life In The Country," "Algit News Vol. 1, Issue 2," and "Algit News"; reprints of letter to Mr. Joseph M. Ronan, and reprints of letter headed "State of Montana" to Mr. M. Ottesen.

RESULTS OF INVESTIGATION: The accompanying labeling was received by the dealer at Spokane, Wash., from Larry Ottesen, Seattle, Wash.

LIBELED: 3-23-59, E. Dist. Wash.

CHARGE: 502(a)—when shipped and while held for sale, the labeling accompanying the article contained false and misleading representations that the article was an adequate and effective treatment for establishing and maintaining good health, digestion, and reproduction, bloom of health as indicated by slick, shiny hair, increased activity and eagerness for feed, eliminating Bangs disease, increasing the hemoglobin, curing anemia and preventing pneumonia of herds, obtaining brighter combs, reduced mortality, glossy feathers, superior health, and eliminating hemorrhagic conditions of chickens; eliminating fin rot of trout; hangovers and poor eyesight of man; obtaining bloom, slicker hides, good health and vigor of hogs; reducing the mortality rate of turkeys; and correcting animal diseases generally.

The libel also charged that the article was misbranded under the provisions of the law applicable to foods as reported in notices of judgment on foods.

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\*See also Nos. 5908, 5920, 5921.



**DISPOSITION:** 3-27-59. Consent—claimed by Algit Kelp Meal Distributing, Inc., Spokane, Wash., and relabeled.

**5938. Hexidine.** (F.D.C. No. 42705. S. No. 26-194 P.)

**QUANTITY:** 141 jars at Sioux City, Iowa.

**SHIPPED:** 3-25-58 and 8-21-58, from Kansas City, Mo., by National Laboratories Corp.

**LABEL IN PART:** "One Pound Hexidine 20 (Improved) each ounce contains Hexidine 20 Grs. (Methenamine Tetra-Iodide) Aromatics and Sodium Chloride Q.S. Manufactured by the National Laboratories Corp. Kansas City."

**LIBELED:** On or about 2-17-59, N. Dist. Iowa.

**CHARGE:** 502(a)—when shipped, the bottle label contained false and misleading representations that the article was an adequate and effective treatment for overcoming sterility, respiratory conditions, mastitis, and low-grade infections in cattle and as a tonic and alterative in cattle, horses, hogs, and sheep.

**DISPOSITION:** 3-17-59. Default—destruction.

**5939. Worm-Kill.** (F.D.C. No. 42109. S. No. 43-019 P.)

**QUANTITY:** 38 5-lb. bags at Salt Lake City, Utah.

**SHIPPED:** 7-31-58, from Durango, Colo., by Colorado Livestock Chemical Co.

**LABEL IN PART:** (Bag) "WORM-KILL THE ALL PURPOSE WORMER \* \* \*  
**CONTENTS:** NICOTINE, SULFUR, POTASH, COPPERAS, PHENOTHIAZINE."

**ACCOMPANYING LABELING:** Leaflet entitled "WORM-KILL THE ALL PURPOSE WORMER."

**LIBELED:** 9-19-58, Dist. Utah.

**CHARGE:** 502(a)—when shipped, the labeling contained false and misleading representations that the article was effective for treating all types of worm infestations in livestock and poultry and preventing infestations by ticks and lice in livestock and poultry.

**DISPOSITION:** 3-12-59. Default—destruction.

**5940. Worm capsules (veterinary).** (F.D.C. No. 42572. S. Nos. 37-349/50 P.)

**QUANTITY:** 24,000 capsules in cartons of 8,000 capsules each, and 2 jars, each containing 200 capsules, at Richmond, Mo., in possession of Hewitt's Hatchery & Feed Co.

**SHIPPED:** 5-22-58, from Detroit, Mich.

**LABEL IN PART:** (Ctn.) "Special Capsules \* \* \* Ingredients in each capsule: Oil Chenopodium NG 86.7 mg. Rectified Turpentine Oil NF 86.8 mg. Kamala Powder 171.6 mg. Castor Oil USP 344.9 mg."; (jar) "Hewitt's Worm Capsules."

**RESULTS OF INVESTIGATION:** The capsules in the jars were repackaged by the dealer from bulk stock shipped as described above. The jar label bore no statement of the quantity of contents.

**LIBELED:** 12-16-58, W. Dist. Mo.

**CHARGE:** 502(a)—while held for sale, the jar label of the article contained false and misleading representations that the article was an adequate and

effective treatment for removal of tapeworms and cecal worms in poultry; and 502(b)(2)—the jar label failed to bear an accurate statement of the quantity of contents.

DISPOSITION: 5-7-59. Consent—claimed by Albert Hewitt, Richmond, Mo., and relabeled.

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Devices	<sup>2</sup> 5906, 5914-5919, 5932-5936	Rheumatism, remedies for.	
Dexobese timed disintegration		Neuritis, remedies for. <i>See</i>	
capsules	5911	Rheumatism, remedies for.	
Diuretic	5929	Para Barb 3 capsules	5912
Liquid	5931	Dex Fifteen capsules	5912
Ebicol, Elixir	5928	Pega Palo vine	5902
Electronic devices	<sup>2</sup> 5906	Penicillin, procaine, stockade	5920
Elixir Ebicol	5928	Procaine penicillin, stockade	5920
Estrogen tablets, conjugated	5910	Prophylactics, rubber	5914-5918
Estrogenic substance	5909	Radioclast Model 40	<sup>2</sup> 5906
conjugated	5910	Model P	<sup>2</sup> 5906
Eucalyptus oil compound	5924	Reducing devices	5933-5935
First Aid for Headache	5922	Relax-A-Pad device	5933
Gastric ulcers, remedy for	5931	Rheumatism, remedies for	5924, 5926,
Gout, remedies for. <i>See</i> Rheu-			5930
matism, remedies for.		devices for	5933, 5934, 5936
Groff's Artha-Tone	5926	Royal jelly capsules	5927
Health-O-Pedic Chairs	5936	Sciatica, remedies for. <i>See</i>	
Heart conditions, remedy for	5930	Rheumatism, remedies for.	
Herbs for Health	<sup>3</sup> 5903	Sinusitis, remedy for	5924
Hexadin	5908	Skin disorders, remedies for	<sup>1</sup> 5901,
			5905

<sup>1</sup> (5901) Injunction contested. Contains findings of fact and conclusions of law.

<sup>2</sup> (5906) Seizure contested.

<sup>3</sup> (5903) Injunction issued.

<sup>4</sup> (5904) Contempt of injunction.

	N.J. No.		N.J. No.
Slim-Trim Lounge.....	5935	Vibrating devices.....	5933-5936
Thermometers, clinical.....	5919	Weatol .....	5908
Ulcers, gastric, remedy for.....	5931	Worm capsules (veterinary).....	5940
Veterinary preparations.....	5907, 5908, 5920, 5921, 5937-5940	Worm-Kill .....	5939

## SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

	N.J. No.		N.J. No.
A-1 Import Co.:		Evans, J. L.:	
Pega Palo vine.....	5902	herbal drugs.....	<sup>3</sup> 5903
Aitchison Laboratories:		Forward Club:	
First Aid for Headache.....	5922	herbal drugs.....	<sup>3</sup> 5903
Algea Produkter A.S.:		Goodwear Rubber Co.:	
Algit Norwegian Kelp Meal..	5937	rubber prophylactics.....	5915, 5916
B & E Distributing Co.:		Halsom Drug Co.:	
Pega Palo vine.....	5902	amphetamine tablets.....	5925
Botab Co.:		Harvest Brand, Inc.:	
Botab tablets and Diuretic		stockade procaine penicillin..	5920
Liquid.....	5931	Health Food Jobbers, Inc.:	
Botanic Drug Co.:		lecithin tablets.....	5930
Dr. Navaun's Tablets.....	5929	Health-O-Pedic Chair Co.:	
Caldwell & Bloor Co.:		Health-O-Pedic Chairs.....	5936
Martabs No. 2.....	5913	Hermelin, Victor M., & Co.:	
Casco Products Corp.:		Desarin tablets.....	5909
Casco Thermal Massager.....	5934	Hewitt's Hatchery & Feed Co.:	
Chase Mfg. Co.:		worm capsules (veterinary)...	5940
clinical thermometers.....	5919	Keystone Laboratories. <i>See</i>	
Chex Co.:		Soles, Otto.	
First Aid for Headache.....	5922	Killashun Sales Div. of the Ak-	
Colorado Livestock Chemical Co.:		well Corp.:	
Worm-Kill.....	5939	rubber prophylactics.....	5914, 5915
Consumer Drug Corp.:		Killian Mfg. Div. of the Akwell	
Dermaden.....	5905	Corp.:	
Curts Laboratories:		rubber prophylactics.....	5914
Hexadin, Arsan Powder, and		Ljubljana, Mercator:	
Weatol.....	5908	mineral water.....	5923
Dean & Lee:		Lustgarten Laboratories, Inc.:	
medicated feed.....	5907, 5921	conjugated estrogen tablets..	5910
De Caribe Rubber Co.:		Matteson, Glenn, Co., Inc.:	
rubber prophylactics.....	5917, 5918	Groff's Artha-Tone.....	5926
Delavau, J. W. S., Co., Inc.:		Merritt Corp.:	
amphetamine tablets.....	5925	Clarimycin.....	<sup>1</sup> 5901
Delmar Pharmacal Corp.:		Mustiez Products:	
Dexobese timed disintegration		eucalyptus oil compound.....	5924
capsules.....	5911	National Laboratories Corp.:	
Para Dex Fifteen capsules and		Hexidine.....	5938
Para Barb 3 capsules.....	5912	National Lecithin, Inc.:	
Electronic Instrument Co.:		lecithin tablets.....	5930
electronic devices.....	<sup>2</sup> 5906		

<sup>1</sup> (5901) Injunction contested. Contains findings of fact and conclusions of law.<sup>2</sup> (5906) Seizure contested.<sup>3</sup> (5903) Injunction issued.



	N.J. No.		N.J. No.
National Sanitary Sales, Inc.:		rubber prophylactics-----	5916
rubber prophylactics-----	5917, 5918	Slim-Trim Mfg. Co.:	
Pitman Chemical Laboratories,		Slim-Trim Lounge-----	5935
Inc.:		Soles, Otto:	
eucalyptus oil compound-----	5924	herbal drugs-----	<sup>2</sup> 5903, <sup>4</sup> 5904
Raymond Pectoral Plaster Co.,		Tennessee Royal Jelly Co.:	
Inc.:		royal jelly capsules-----	5927
medicated plasters-----	5932	Thompson, Marvin R., Inc.:	
Reed, J. V., D.C.:		Elixir Ebicol-----	5928
electronic devices-----	<sup>2</sup> 5906	Tivoli Imports:	
Relax-A-Cushion, Inc.:		mineral water-----	5923
Relax-A-Pad device-----	5933	Wright, George A., Inc.:	
Shunk, L. E., Latex Prod. of the		Botab tablets and Diuretic Liq-	
Akwel Corp.:		uid-----	5931

<sup>2</sup> (5906) Seizure contested.<sup>3</sup> (5903) Injunction issued.<sup>4</sup> (5904) Contempt of injunction.

# U.S. Department of Health, Education, and Welfare

## FOOD AND DRUG ADMINISTRATION

### NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

5941-5980

### DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs which are required at time of interstate shipment to bear a label containing the statement "Caution: Federal law prohibits dispensing without prescription," and which were dispensed after such shipment without a prescription or by refilling a prescription without authorization. This dispensing was contrary to Section 503(b) (1) and thereby resulted in the dispensed drugs being misbranded while held for sale.

Published by direction of the Secretary of Health, Education, and Welfare.

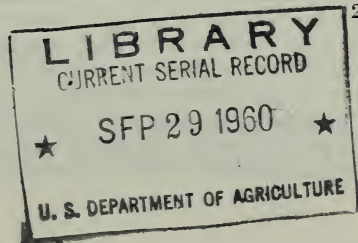
GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D.C., August 24, 1960

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## VIOLATIVE SALES OF PRESCRIPTION DRUGS

5941. (F.D.C. No. 43250. S. Nos. 38-129/30 P.)

INFORMATION FILED: 2-5-60, E. Dist. Mo., against **George F. Huff, St. Ann, Mo.**

CHARGE: Between 2-17-59 and 3-9-59, *amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 2-19-60. \$1,000 fine, plus costs, and 30 days imprisonment.

5942. (F.D.C. No. 43244. S. Nos. 50-609/12 P.)

INFORMATION FILED: 10-7-59, E. Dist. Ky., against **Floyd Rollins, t/a Shamrock Texaco Service, Somerset, Ky.**

CHARGE: Between 6-4-59 and 6-11-59, *amphetamine sulfate tablets* were dispensed 4 times without a prescription.

PLEA: Guilty.

DISPOSITION: 4-4-60. 1 year imprisonment.

5943. (F.D.C. No. 43710. S. Nos. 10-919/20 P.)

INFORMATION FILED: 3-28-60, W. Dist. N. Y., against **Thomas R. Barnes, Cleveland, Ohio.**

CHARGE: On 6-25-59, *amphetamine sulfate tablets* and *amphetamine sulfate capsules* were each dispensed once without a prescription at Ripley, N.Y.

PLEA: Guilty.

DISPOSITION: 4-18-60. Sentence of 2 years imprisonment.

5944. (F.D.C. No. 42416. S. Nos. 15-038/40 P.)

INFORMATION FILED: 1-20-59, W. Dist. Ky., against **Mrs. Mildred Bolding, Franklin, Ky.**

CHARGE: Between 7-8-58 and 7-9-58, *amphetamine sulfate tablets* were dispensed 3 times without a prescription.

PLEA: Not guilty.

DISPOSITION: On 5-20-59, the case came on for trial before the court and jury and was concluded on 5-21-59 with the return of a verdict of guilty by the jury. On the same day the defendant was fined \$200.

5945. (F.D.C. No. 42398. S. Nos. 23-605 P, 23-609/11 P, 23-613 P.)

INFORMATION FILED: 6-2-59, S. Dist. Calif., against **Bordan's Victory Pharmacy, Inc., Los Angeles, Calif., Harry I. Resnik (president of the corporation) and Edward I. Fisher (pharmacist).**

CHARGE: The information (count 1) alleged that the defendants, since 1-1-57, and continuously thereafter to the date of the filing of the information, did combine, conspire, and agree together and with each other, and with other unknown persons, to commit offenses against the United States with respect to the unlawful dispensing, repackaging, and labeling of *amphetamine sulfate tablets* while held for sale after shipment in interstate commerce into the State of California, thereby causing such drug to become misbranded; and that it was a part of the conspiracy—

(a) to dispense *amphetamine sulfate tablets* without a prescription from a practitioner licensed by law to administer such drug, thereby resulting in the drug being misbranded within the meaning of 503(b) (1);



(b) to repackage and dispense *amphetamine sulfate tablets* in unlabeled containers, such as paper bags, thereby resulting in the drug being misbranded within the meaning of 502(b), 502(e) (1), and 502(f) (1) ;

(c) to purchase at prices varying from \$1.10 to \$1.50 per 1,000 tablets, through wholesale channels, large quantities of *amphetamine sulfate tablets* which had been manufactured outside of California ;

(d) to sell *amphetamine sulfate tablets* in large quantities to customers without a physician's prescription, at varying prices such as \$9.00 for 300 tablets, \$15 for 500 tablets, \$25 for 1,000 tablets, and \$50 for 2,000 tablets; and

(e) to deliver the *amphetamine sulfate tablets* to the customer in unlabeled paper bags and, on request of the customer, to furnish the customer with empty unlabeled paper bags or envelopes for the customer's use in further distribution of the tablets.

It was alleged further, in pursuance of the conspiracy and to effect the objects thereof, that the defendants and their co-conspirators, between 1-29-58 and 2-11-58, had several conversations with Jerry L. Howard and sold *amphetamine sulfate tablets* to Jerry L. Howard on 4 different occasions without a prescription.

The information alleged also (counts 2 to 11 inclusive) that, between 1-30-58 and 2-6-58, *amphetamine sulfate tablets* while held for sale after shipment in interstate commerce were dispensed 5 times without a prescription contrary to Section 503(b) (1) ; and that such tablets were also repackaged and dispensed in unlabeled paper bags resulting in the tablets being misbranded as follows :

502(b)—the drug failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of its contents in terms of numerical count ;

502(e) (1)—the drug did not have a label which bore the common or usual name of the drug; and

502(f) (1)—the drug did not have labeling which bore adequate directions for use.

PLEA: Not guilty by the corporation and Resnik to all counts and by Fisher to counts 1, 8, and 9.

DISPOSITION: The case came on for trial before the court and jury on 8-27-59.

During the trial the court granted a motion for judgment of acquittal on count 1. On 9-8-59, the jury returned a verdict of guilty on counts 2 to 11, inclusive. Thereafter, the court, on 10-13-59, imposed the following sentences: Corporation—\$2,500 fine; Resnik—\$2,500 fine and probation for 2 years; Fisher—\$350 fine and probation for 2 years.

5946. (F.D.C. No. 41162. S. Nos. 77-579 M, 77-582/5 M.)

INFORMATION FILED: 4-4-58, N. Dist. Ga., against Jim T. Harrison, Acworth, Ga.

CHARGE: Between 9-18-57 and 11-1-57, *amphetamine sulfate tablets* were dispensed 5 times without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 7-14-58. Probation for 2 years.

5947. (F.D.C. No. 42036. S. Nos. 13-141/4 P.)

INFORMATION FILED: 11-25-58, N. Dist. Ill., against Liberty Drug Co., a partnership, Chicago, Ill., Nathan Roskin (partner), and Harmon L. Ginsberg (pharmacist).

ALLEGED VIOLATION: Between 3-12-58 and 4-14-58, tablets which had been fabricated in the State of Illinois from amphetamine sulfate powder that had been shipped in interstate commerce, were dispensed 4 times without a prescription.

DISPOSITION: On 12-18-58, the partnership and defendant Roskin entered a plea of not guilty to all counts and defendant Ginsberg entered a plea of not guilty to 3 counts. Thereafter, defendants filed a motion to dismiss and a motion for a bill of particulars. On 4-3-59, the court filed the following memorandum denying defendants' motion to dismiss:

SULLIVAN, *District Judge*: "This is an indictment under Title 21, U.S.C. § 353, which proscribes the dispensing of a drug without the prescription of a physician, when—

because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug \* \* \*

"Defendants have filed a motion to dismiss on several grounds, the most serious of which is that the quoted phrase is in violation of the due process clause in that it is 'vague, indefinite, uncertain and unintelligible to such an extent that the persons sought to be governed by them cannot determine what conduct on their part constitutes a criminal offense.'

"This contention must be overruled. '\* \* \* the provisions of this Act are sufficiently definite to support a criminal charge for the violation of the Act.' (*United States vs. 2600 State Drugs, Inc.*, 235 F. (2d) 913, (7th Cir., 1956), and cases there cited.

"The motion to dismiss will be denied."

On the same day the court granted the motion for bill of particulars in part.

Thereafter, on 7-22-59, defendants changed this plea of not guilty to nolo contendere, and the partnership was fined \$200 and costs; defendant Roskin was fined \$200; and Ginsberg was fined \$150.

5948. (F.D.C. No. 42439. S. Nos. 15-598/9 P, 15-605 P.)

INFORMATION FILED: 3-10-59, S. Dist. Ohio, against Vernon T. Osborne and Edward P. Cogan, Aberdeen, Ohio.

CHARGE: Between 6-24-58 and 7-11-58, *amphetamine sulfate tablets* were dispensed 3 times without a prescription.

PLEA: Guilty by Osborne to all counts and by Cogan to counts 1 and 2.

DISPOSITION: 4-3-59. Each defendant sentenced to 1 year in jail.

5949. (F.D.C. No. 42424. S. Nos. 5-191/2 P.)

INFORMATION FILED: 1-30-59, E. Dist. N.C., against Legrand Lindsay, Hampstead, N.C.

CHARGE: On 10-27-58, *amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 6-18-59. \$100 fine.

5950. (F.D.C. No. 42415. S. Nos. 15-086/7 P, 15-041/3 P.)

INFORMATION FILED: 1-24-59, W. Dist. Ky., against Magdalene Kingery and Hazel Walker, Horse Cave, Ky.

CHARGE: Between 6-4-58 and 7-16-58, *dextro-amphetamine sulfate capsules* were dispensed 4 times and *amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 5-18-59. \$300 fine against each defendant.

5951. (F.D.C. No. 42403. S. Nos. 1-588/9 P, 1-595/6 P, 1-598 P, 1-694 P, 1-698 P, 1-712/3 P.)

INFORMATION FILED: 3-3-59, N. Dist. Ga., against McKinney's Apothecary (a partnership), Decatur, Ga., and William Wingo McKinney (partner), and John Lewis Pledger (partner).

CHARGE: Between 2-28-58 and 3-25-58, *dextro-amphetamine sulfate tablets* (counts 1, 2, and 3) were dispensed 3 times, and *pentobarbital sodium capsules* (counts 4 and 5), *secobarbital sodium capsules* (counts 6 and 7), and *meprobamate tablets* (counts 8 and 9) were each dispensed twice upon requests for prescription refills without authorization by the prescriber.

PLEA: Nolo contendere by partnership to all counts of the information; by McKinney to counts 2, 3, 5, 6, 7, and 9; and by Pledger to counts 1, 3, 4, 7, 8, and 9.

DISPOSITION: 3-30-59. Partnership—\$9 fine; McKinney—\$171 fine; and Pledger—\$170 fine.

5952. (F.D.C. No. 41143. S. Nos. 39-458 M, 39-462/3 M.)

INFORMATION FILED: 3-28-58, M. Dist. N.C., against Ransom Fred Carswell, Jr., Winston-Salem, N.C.

CHARGE: Between 6-6-57 and 6-18-57, *dextro-amphetamine sulfate tablets* were dispensed 3 times upon request for prescription refills without authorization by the prescriber.

PLEA: Guilty.

DISPOSITION: 5-20-58. \$1,000 fine, sentence of 2 years imprisonment suspended, and probation for 2 years.

5953. (F.D.C. No. 42440. S. Nos. 13-601/2 P, 13-807 P.)

INFORMATION FILED: 3-30-59, E. Dist. Wis., against Hiram L. Brooks, t/a Brooks Drug Store and Brooks Super Drug Store, Marinette, Wis., and Carlton Bohman (clerk).

CHARGE: Between 7-28-58 and 8-20-58, *dextro-amphetamine sulfate tablets* were dispensed once and *Ergoapiol with savin capsules* were dispensed twice without a prescription.

PLEA: Guilty by Brooks to the counts involving *Ergoapiol with savin capsules* and by Bohman to the count involving *dextro-amphetamine sulfate tablets*.

DISPOSITION: 1-11-60. Brooks—\$1,000 fine; Bohman—\$250 fine.

5954. (F.D.C. No. 43237. S. Nos. 1-210 P, 1-219 P, 1-249 P.)

INFORMATION FILED: 9-23-59, S. Dist. Ga., against Clarence L. Powell, t/a Wilkes Drug Co., Collins, Ga.

CHARGE: Between 1-12-59 and 3-30-59, *Dexedrine Sulfate tablets* were dispensed twice and *Dexamyl Spansule capsules* were dispensed once without a prescription.



PLEA: Guilty.

DISPOSITION: 11-9-59. \$300 fine and probation for 2 years.

5955. (F.D.C. No. 43208. S. Nos. 906 P, 917 P, 2-352 P, 44-282 P, 44-309 P, 44-314/5 P, 44-317/8 P, 44-331 P.)

INFORMATION FILED: 7-22-59, S. Dist. Ga., against Alton P. Meeks, Sr., t/a Alma Drug Co., Alma, Ga.

CHARGE: Between 10-7-58 and 12-8-58, *Dewedrine Sulfate tablets* and *secobarbital sodium capsules* were each dispensed 4 times upon requests for prescription refills without authorization by the prescriber, and *Pentids tablets* were dispensed twice without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 9-21-59. \$500 fine and probation for 2 years.

5956. (F.D.C. No. 41724. S. Nos. 65-527/8 M, 65-530/2 M.)

INFORMATION FILED: 7-8-58, E. Dist. Ky., against McAdams & Morford, Inc., Lexington, Ky., Francis E. Crowley (pharmacist and manager for the corporation), Billy Ray Gaines (pharmacist), and J. Thomas Manuel (pharmacist).

CHARGE: Between 10-6-57 and 10-10-57, *Dewedrine Sulfate tablets* were dispensed 5 times upon requests for a prescription refill without authorization from the prescriber.

PLEA: Not guilty by the corporation and Crowley on all counts; by Manuel on count 3; and by Gaines on count 4.

DISPOSITION: The case came on for trial before the court and jury on 5-25-59. On 5-28-59, the jury by its verdict acquitted all the individual defendants, and the corporation was found guilty on counts 2, 3, 4, and 5 and acquitted on count 1.

Thereafter, on 6-3-59, the corporate defendant filed a motion to set aside the verdict of guilty against the corporation, which motion was overruled. On 10-19-59, the corporation was fined \$2,000 and costs.

5957. (F.D.C. No. 42026. S. Nos. 3-511/16 P.)

INFORMATION FILED: 11-13-58, District of Columbia, against Wesley Heights Pharmacy, Inc., Washington, D.C., and Arnold S. Meier (pharmacist).

CHARGE: Between 4-22-58 and 5-31-58, *Dewedrine Sulfate tablets* were dispensed 3 times upon requests for a prescription refill without authorization from the prescriber and 3 times without a prescription.

PLEA: Not guilty by the corporation and the individual.

DISPOSITION: The case came on to trial before the court and jury. On 2-5-59, the jury returned a verdict of not guilty against the corporation and the court declared a mistrial as to defendant Meier. Subsequently the case against Meier was set for trial again. On 11-16-59, before the case came on to trial, the defendant, Meier, pleaded guilty to 2 counts of dispensing *Dewedrine Sulfate tablets* without a prescription and was sentenced to pay a fine of \$1,000 or serve 180 days in jail on each count, with the sentences to run concurrently.

5958. (F.D.C. No. 41181. S. Nos. 81-082 M, 81-087/8 M, 81-093/4 M, 81-098/9 M.)

INFORMATION FILED: 4-25-58, E. Dist. Va., against Bell Drugs, Inc., Arlington, Va., Arthur Salus (president and treasurer of the corporation), and Theodore Casey Moore (pharmacist).

CHARGE: Between 8-23-57 and 10-13-57, *Dexedrine Sulfate tablets* (counts 1, 2, and 6) were dispensed 3 times and *Tuinal capsules* (counts 3 and 4) were dispensed twice upon requests for prescription refills without authorization by the prescriber, and *Gantrisin tablets* (counts 5 and 7) were dispensed twice without a prescription.

PLEA: Guilty by the corporation to counts 1 and 2, and by Salus to count 1. Not guilty by Moore to counts 2 through 7.

DISPOSITION: On 11-19-59, the case against defendant Moore came on for trial before the court and the jury, and, on 11-20-59, the jury returned a verdict of guilty.

On 3-31-60, the corporation was fined \$500; Salus was fined \$1,000 and placed on probation for 2 years; and Moore was fined \$1,200 and placed on probation for 2 years.

5959. (F.D.C. No. 43234. S. Nos. 1-905 P, 1-909 P, 1-922/3 P, 1-931/2 P, 44-384/5 P.)

INFORMATION FILED: 10-15-59, W. Dist. N.C., against Thomas H. Lever, Sr., t/a Carolina Pharmacy, Charlotte, N.C., and Thomas H. Lever, Jr. (employee).

CHARGE: Between 7-9-58 and 9-15-58, *Dexedrine Sulfate tablets* were dispensed 5 times and *pentobarbital sodium capsules* were dispensed 3 times upon requests for prescription refills without authorization by the prescriber.

PLEA: Guilty by Lever, Sr. to all counts and by Lever, Jr. to 3 counts.

DISPOSITION: 4-4-60. Each defendant fined \$350 and placed on probation for 2 years.

5960. (F.D.C. No. 43263. S. Nos. 42-646/50 P, 49-286/9 P.)

INDICTMENT RETURNED: 2-10-60, E. Dist. Wash., against Harry W. Tichacek, t/a Union Gap Pharmacy, Union Gap, Wash.

CHARGE: Between 11-5-58 and 12-3-58, *Dexedrine Sulfate tablets* were dispensed 5 times and *secobarbital sodium capsules* were dispensed 4 times without a prescription.

PLEA: Guilty.

DISPOSITION: 3-28-60. \$1,000 fine and probation for 1 year.

5961. (F.D.C. No. 43265. S. Nos. 54-229/30 P, 54-233 P, 54-235/6 P, 54-302 P.)

INFORMATION FILED: 10-26-59, E. Dist. Mo., against Arthur E. Sandvoss, t/a Sandvoss Drug Co., St. Louis, Mo.

CHARGE: Between 12-30-58 and 1-22-59, *Seconal Sodium capsules* were dispensed twice upon request for prescription refills without authorization by the prescriber, and *Meticorten tablets* were dispensed twice and *meprobamate tablets* and *thyroid tablets* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 11-25-59. The defendant was sentenced to jail for 6 months, fined \$1,200, and placed on probation for 1 year.

5962. (F.D.C. No. 42478. S. Nos. 45-079 P, 45-103 P, 45-107 P.)

INFORMATION FILED: 9-30-59, Dist. Colo., against Zachey N. Hopper, t/a Med-Row Pharmacy, Pueblo, Colo., Arthur M. Vallejos (pharmacist) and Rose Marie Baker (pharmacist).

CHARGE: Between 5-6-58 and 11-20-58, *Seconal Sodium capsules* were dispensed once without a prescription, and *Synatan tablets* were dispensed twice upon requests for prescription refills without authorization by the prescriber.

PLEA: Nolo contendere by Hopper to the count involving the *Seconal Sodium capsules* and to one count involving the *Synatan tablets*; by Vallejos and Baker each to one count involving *Synatan tablets*.

DISPOSITION: The defendants filed motions for dismissal of the information on the grounds that (1) two persons were charged jointly with doing a single act, and that such was a misjoinder of defendants so confusing as to deny each of the defendants due process of law, (2) each charge was so ambiguous and confused as to lead to doubt as to the charge as well as the section of the law under which the charge was brought; and that each defendant was entitled to know the exact facts that led to the charge as laid in the complaint, and (3) that the complaint did not state facts sufficient upon which a criminal conviction could be had. The motions were denied on 12-4-59. Thereafter, the defendants entered pleas as indicated above. On 3-11-60, Hopper was fined \$300 and Baker was fined \$150. On 3-18-60, Vallejos was fined \$150.

5963. (F.D.C. No. 43671. S. Nos. 47-644 P, 47-647 P, 47-976 P, 48-163 P.)

INFORMATION FILED: 12-4-59, Dist. Mass., against Merit Super Drug, Inc., and Louis A. Katz (treasurer), Boston, Mass.

CHARGE: Between 12-10-58 and 3-16-59, *pentobarbital sodium capsules* were dispensed 1 time and *penicillin tablets* were dispensed 3 times without a prescription.

PLEA: Guilty.

DISPOSITION: 2-8-60. Corporation—\$500 fine; Katz—6 months imprisonment which was suspended, and probation for 2 years.

5964. (F.D.C. No. 43672. S. No. 46-163/8 P.)

INFORMATION FILED: About 11-12-59, N. Dist. Miss., against Joseph Boyd Adams, t/a People's Drug Store, Vardaman, Miss.

CHARGE: Between 1-20-59 and 1-26-59, *thyroid tablets* and *Medrol tablets* were each dispensed twice, and *penicillin tablets* and *phenobarbital tablets* were each dispensed once without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 2-5-60. \$600 fine.

5965. (F.D.C. No. 43213. S. Nos. 43-475 P, 43-479 P.)

INFORMATION FILED: 7-20-59, Dist. Colo., against Farmer's Pharmacy (a partnership), Cortez, Colo., and Carl B. Skoog (a partner).

CHARGE: Between 9-21-58 and 9-23-58, *Aristocort tablets* and *Dexedrine Sulfate tablets* were each dispensed once upon requests for refills of prescriptions without authorization by the prescribers.

PLEA: Guilty.

DISPOSITION: 9-11-59. Partnership fined \$200 and individual fined \$300.



5966. (F.D.C. No. 42397. S. Nos. 28-304/8P.)

INFORMATION FILED: 12-12-58, N. Dist. Ala., against **Hodges Drug Store (a partnership)**, **Scottsboro, Ala.**, **Charles E. Hodges (partner)**, and **Ethridge B. Thompson (pharmacist)**.

CHARGE: Between 4-22-58 and 4-28-58, *Lotusate tablets* (counts 1, 3, and 4) were dispensed 3 times and *Compocillin-V tablets* (counts 2 and 5) were dispensed twice upon requests for prescription refills without authorization by the prescriber.

PLEA: Guilty by the partnership to all counts; by Hodges to counts 1, 2, and 3; and by Thompson to counts 4 and 5.

DISPOSITION: 1-30-59. Each defendant fined \$200.

5967. (F.D.C. No. 42031. S. Nos. 35-513 P, 35-515 P, 35-517 P, 35-519 P.)

INFORMATION FILED: 9-29-58, E. Dist. Pa., against **Martin Katz, t/a Martin's Drugs, Philadelphia, Pa.**

CHARGE: Between 1-27-58 and 2-27-58, *Achromycin-SF capsules* (count 1) and *Achromycin capsules* (count 2) were each dispensed once and *Tuinal capsules* (counts 3 and 4) were dispensed twice without a prescription.

PLEA: Not guilty.

DISPOSITION: The case came on for trial before a court and jury on 3-16-59, at which time counts 1 and 2 were dismissed on grounds of entrapment. On 3-18-60, the jury returned a verdict of guilty to counts 3 and 4. Thereafter, the defendant filed motions for acquittal on the ground of entrapment and for a new trial. The motions were denied on 3-31-60, and, on 4-19-60, the defendant was fined \$250.

5968. (F.D.C. No. 41173. S. Nos. 76-917 M, 76-922 M, 76-925 M, 76-928 M, 76-933 M.)

INFORMATION FILED: 5-27-58, N. Dist. Ga., against **Albert Francis Moore, t/a Moore's Pharmacy, Cedartown, Ga.**, and **Wilburn Lee Brown (pharmacist)**.

CHARGE: Between 7-11-57 and 8-8-57, *Tuinal capsules* were dispensed 5 times upon requests for prescription refills without authorization by the prescriber.

PLEA: Nolo contendere by Moore to all counts and by Brown to counts 1, 3, and 5.

DISPOSITION: 11-4-59. Moore fined \$250 and Brown fined \$75. Each defendant placed on probation for 1 year.

5969. (F.D.C. No. 43052. S. Nos. 1-190 P, 1-193 P, 1-886 P, 2-629 P, 2-635/6 P, 2-643/4 P, 2-649/50 P.)

INFORMATION FILED: 4-17-59, W. Dist. N.C., against **Allen Drug Co. (a partnership)**, **Cherryville, N.C.**, and **Harry H. Allen, Sr. and William Franklin Allen (pharmacists and partners in the partnership)**.

CHARGE: Between 4-29-58 and 6-19-58, *Pen-Vee tablets* (counts 1, 2, 4, and 6), and *Seconal Sodium capsules* (counts 3, 5, 7, and 8) were each dispensed 4 times and *Nembutal capsules* (counts 9 and 10) were dispensed twice upon request for prescription refills without authorization by the prescribers.

PLEA: Guilty, by the partnership to all counts; by Harry H. Allen, Sr. to counts 1, 2, 3, 8, and 10; and by William Franklin Allen to counts 4, 5, 6, 7, and 9.

DISPOSITION: 10-5-59. A collective fine of \$1,000 was assessed against the partnership and the individuals. Individual defendants were each placed on probation for 3 years.

5970. (F.D.C. No. 43246. S. Nos. 22-101 P, 22-103/6 P.)

INFORMATION FILED: 10-14-59, Dist. Nebr., against Harry G. Williams, Omaha, Nebr.

CHARGE: Between 2-10-59 and 4-10-59, *methamphetamine hydrochloride tablets* were dispensed 4 times and *Benzedrine Sulfate tablets* were dispensed once without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 10-29-59. \$1,000 fine, plus costs, 1 year imprisonment which was suspended, and probation for 3 years.

On 1-5-60, a petition was filed for revocation of probation imposed against the defendant. The application charged that the defendant, on 11-28-59, dispensed a number of *methamphetamine hydrochloride tablets* without a prescription. After a hearing on 1-6-60, the court found the defendant had violated the conditions of his probation. Thereupon the court revoked the order of probation previously entered and sentenced the defendant to 1 year imprisonment.

5971. (F.D.C. No. 43226. S. Nos. 3-738 P, 5-026 P.)

INFORMATION FILED: 9-29-59, Dist. Md., against Duvall Pharmacy, Inc., Baltimore, Md., and Leon L. Tattar (president and treasurer of the corporation).

CHARGE: Between 1-5-59 and 1-30-59, *V-Cillin K tablets* (count 1) and *Nembutal capsules* (count 2) were each dispensed once upon requests for prescription refills without authorization from a prescriber.

PLEA: Guilty by the corporation to both counts and by Tattar to count 1.

DISPOSITION: 1-15-60. Corporation—\$900 fine; Tattar—\$300 fine, plus costs to be prorated between the defendants.

5972. (F.D.C. No. 43106. S. Nos. 48-728 M, 79-307 M, 82-815 M, 3-465 P, 35-130 P.)

INFORMATION FILED: 2-19-60, E. Dist. Pa., against Harvey-Pittenger Co., Inc., and Eugene L. Cohen, t/a Wyanel Laboratories, Philadelphia, Pa.

ALLEGED VIOLATION: Between 7-15-57 and 1-15-58, the defendants caused quantities of *Gardophen elixir*, *Thriocaine Lotion*, *Rauprote tablets*, *Piptelate tablets*, and *Triophen tablets* to be introduced and delivered for introduction into interstate commerce by various drug manufacturers at Philadelphia, Sellersville, and Allentown, Pa., for delivery to Chicago, Ill., New York, N.Y., Cleveland, Ohio, Lynchburg, Va., and Collingswood, N.J.

LABEL IN PART: "Gardophen (Elixir Hyoscyamine Comp.) Each 5cc (1 teaspoonful) contains: Phenobarbital ( $\frac{1}{4}$  gr.) 16.20 mg."; "3 Fluid ounces THRIOCAINE LOTION CONTAINS: TYROTHRIN 0.01% BENZOCAINE 2.0%"; "RAUPROTE 100 TABLETS Each tablet contains: Rauwolfia Serpentina 50 mg. Protoveratrine A and B 0.2 mg."; "PIPTELATE (BRAND OF PIPERAZINE CITRATE) 100 TABLETS Each tablet contains the equivalent of: PIPERAZINE HEXAHYDRATE . . . 250 mg."; and "TRIOPHEN 1000 Tablets Each tablet contains: Phenobarbital  $\frac{1}{2}$  gr. (Warning: \* \* \*) Atropine Sulfate 1/500 gr. Magnesium Trisilicate 7 gr."

**RESULTS OF INVESTIGATION:** The drugs involved were manufactured by various companies. After manufacture, but before final packaging, samples of the drugs were submitted to the defendants for analysis in order to determine if the strength of the drugs met the standards which they purported and were represented to possess. The defendants submitted reports to the companies indicating that the samples had been analyzed and were found to be of proper strength. In reliance thereon, the manufacturing companies packaged the drugs and shipped them in interstate commerce. Subsequent analysis by the Food and Drug Administration showed that the drugs differed in strength from that which they were represented to possess.

**CHARGE:** 501(c)—when shipped, the strength of the articles differed from that which they purported and were represented to possess in that the article of *Gardophen elixir* contained more than the 16.20 mg. of phenobarbital in each 5 cc. which it was represented to possess; the article of *Thriocaine Lotion* contained more than 0.01 percent of Tyrothricin per 3 fl. ozs. which it was represented to possess; the *Rauprote tablets* contained less than the 0.2 mg. of Protoveratrine A and B per tablet which they were represented to possess; the *Piptelate tablets* contained less than the equivalent of 250 mg. of piperazine hexahydrate per tablet, which they were represented to possess; and the *Triophen tablets* contained less than  $\frac{1}{2}$  gr. of phenobarbital per tablet which they were represented to possess.

**PLEA:** Nolo contendere.

**DISPOSITION:** 2-19-60. Corporation—\$25 fine; Cohen—\$1,000 fine, 1 year imprisonment which was suspended, and probation for 3 years.

5973. (F.D.C. No. 43697. S. Nos. 50-861/5 P.)

**INFORMATION FILED:** 12-8-59, N. Dist. Ind., against Lyle V. Prendergast, t/a Lyle's Pharmacy, Cedar Lake, Ind.

**CHARGE:** Between 1-22-59 and 3-5-59, *Miltown tablets* and *Dewedrine Spansule capsules* were dispensed twice each and *AM Plus capsules* were dispensed once without a prescription.

**PLEA:** Guilty.

**DISPOSITION:** 12-22-59. \$250 fine, plus costs.

5974. (F.D.C. No. 43240. S. Nos. 31-012 P, 32-852 P, 33-106 P.)

**INFORMATION FILED:** 9-29-59, Dist. N.J., against Raymond S. Bennett, t/a Bennett's Pharmacy, Maplewood, N.J.

**CHARGE:** Between 3-20-59 and 4-23-59, *pentobarbital sodium capsules* were dispensed once without a prescription, and *Dewedrine Spansule capsules* and *Butisol Sodium Elixir* were each dispensed once upon requests for prescription refills without authorization from a prescriber.

**PLEA:** Nolo contendere.

**DISPOSITION:** 12-11-59. Probation for 2 years.

5975. (F.D.C. No. 42028. S. Nos. 2-385 P, 2-396 P, 2-401/3 P.)

**INFORMATION FILED:** 10-20-58, S. Dist. Fla., against Solomon George Saig, t/a St. Clair Grocery, Jacksonville, Fla.

**CHARGE:** Between 2-4-58 and 2-18-58, *Nembutal capsules* and *Tuinal capsules* were each dispensed once and *Dewedrine Spansule capsules* were dispensed 3 times without a prescription.



PLEA: Guilty.

DISPOSITION: The case was transferred to the United States District Court for the Eastern District of Michigan for a plea of guilty. On 1-15-60, the defendant was sentenced to 6 months imprisonment.

5976. (F.D.C. No. 38602. S. Nos. 864/5M, 868 M.)

INFORMATION FILED: 6-21-56, S. Dist. Fla., against **Mussa C. Bateh** (pharmacist), and **Issa C. Bateh** (clerk), Jacksonville, Fla.

CHARGE: Between 7-10-55 and 8-13-55, *Benzedrine Sulfate tablets* were dispensed once and *capsules containing a mixture of secobarbital sodium and amobarbital sodium* were dispensed twice without a prescription.

PLEA: Guilty by Issa Bateh to one count involving *capsules containing a mixture of secobarbital sodium and amobarbital sodium*, and by Mussa Bateh to the other two counts.

DISPOSITION: 4-26-57. Issa Bateh—\$200 fine; 1-22-60, Mussa Bateh—9 months imprisonment.

5977. (F.D.C. No. 43257. S. Nos. 47-657 P, 47-660 P, 47-961 P, 47-972/4 P, 47-977/9 P.)

INFORMATION FILED: 12-4-59, Dist. Mass., against **Henry H. Rendell**, Medford, Mass.

CHARGE: Between 1-22-59 and 3-10-59, *Nembutal capsules* were dispensed 4 times, *Tuinal capsules* were dispensed twice, and *Amsustain tablets*, *Dexedrine Spansule capsules*, and *Seconal Sodium capsules* were each dispensed once without a prescription.

PLEA: Not guilty.

DISPOSITION: The case came on for trial before the court and jury on 3-1-60, and, on 3-3-60, the jury returned a verdict of guilty. On 4-18-60, the defendant was sentenced to 6 months in jail which was suspended and he was placed on probation for 3 years.

5978. (F.D.C. No. 42029. S. Nos. 2-384 P, 2-394 P, 2-398 P, 2-404 P, 2-408 P.)

INFORMATION FILED: 10-20-58, S. Dist. Fla., against **Albert Younan**, Jacksonville, Fla.

CHARGE: Between 2-4-58 and 3-5-58, *Benzedrine Sulfate tablets* were dispensed 5 times without a prescription.

PLEA: Guilty.

DISPOSITION: 4-8-60. 6 months in prison.

5979. (F.D.C. No. 39833. S. Nos. 22-053 M, 22-055/6 M, 37-962/3 M.)

INFORMATION FILED: 3-15-57, N. Dist. N.Y., against **Jacob Baurle**, (store manager and pharmacist) and **LeRoy R. Tesiero** (pharmacist), Schenectady, N. Y.

CHARGE: Between 1-17-56 and 1-25-56, *capsules containing a mixture of secobarbital sodium and amobarbital sodium* (counts 1 and 3) and *Gantrisin tablets* (counts 2 and 4) were each dispensed twice upon request for prescription refills without authorization from the prescriber, and *Dexedrine Sulfate tablets* (count 5) were dispensed once without a prescription.

PLEA: Guilty by Baurle to all counts and by Tesiero to counts 1, 3, 4, and 5.

DISPOSITION: 5-6-57. Baurle—\$500 fine; Tesiero—\$400 fine.

5980. (F.D.C. No. 41714. S. Nos. 43-480 M, 84-124/5 M.)

INDICTMENT RETURNED: 1-14-59, E. Dist. Mo., against Isador Kammer, t/a Belt Avenue Pharmacy, St. Louis, Mo.

CHARGE: Between 8-8-57 and 10-25-57, *secobarbital sodium capsules* were dispensed once without a prescription, and *dextro-amphetamine sulfate tablets* were dispensed twice upon requests for a prescription refill without authorization from the prescriber.

PLEA: Guilty.

DISPOSITION: 2-4-60. \$600 fine.

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	N.J. No.		N.J. No.
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-SF capsules-----	<sup>1</sup> 5967	tablets-----	<sup>3</sup> 5970
AM Plus capsules-----	5973	Meticorten tablets-----	5961
Amphetamine, dextro-, sulfate		Miltown tablets-----	5973
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sulfate tablets---	5951-5953, 5980		5971, 5975, <sup>1</sup> 5977
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Dexedrine Spansule capsules---	5973-	barbital sodium, capsules	
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Sulfate tablets-----	<sup>1</sup> 5954-		5979
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nobarbital tablets-----	5964	tal capsules-----	5969

<sup>1</sup> (5944, 5945, 5956, 5957, 5967, 5977) Prosecution contested.

<sup>2</sup> (5947) Prosecution contested. Contains opinion of the court.

<sup>3</sup> (5970) Violation of parole.

	N.J. No.		N.J. No.
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		Gaines, B. R.:	
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<sup>1</sup> (5944, 5945, 5956, 5957, 5967, 5977) Prosecution contested.<sup>2</sup> (5947) Prosecution contested. Contains opinion of the court.



	N.J. No.		N.J. No.
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<sup>1</sup> (5944, 5945, 5956, 5957, 5967, 5977) Prosecution contested.<sup>2</sup> (5947) Prosecution contested. Contains opinion of the court.

	N.J. No.		N.J. No.
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<sup>1</sup> (5944, 5945, 5956, 5957, 5967, 5977) Prosecution contested.

<sup>2</sup> (5947) Prosecution contested. Contains opinion of the court.

<sup>3</sup> (5970) Violation of parole.

## U.S. Department of Health, Education, and Welfare

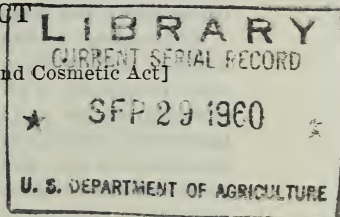
## FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD,  
DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

5981-6000

## DRUGS AND DEVICES



The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were adulterated or misbranded within the meaning of the Act when introduced into and while in interstate commerce or while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings in which decrees of condemnation were entered by default or by consent and (2) a criminal proceeding terminated upon a plea of guilty. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation, and the criminal proceedings are against the *firms* or *individuals* charged to be responsible for violations.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs*.

WASHINGTON, D.C., September 7, 1960.

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\*For drugs in violation of prescription labeling requirements, see No. 5981; for omission of, or unsatisfactory, ingredient statements, see Nos. 5982, 5988.



SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN  
VIOLATIONS REPORTED IN D.D.N.J. 5981-6000

*Adulteration*, Section 501(b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopoeia), and its strength differed from the standard set forth in such compendium; Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength differed from, or its purity or quality fell below, that which it purported or was represented to possess.

*Misbranding*, Section 502(a), the labeling of the article was false and misleading; Section 502(e) (2), the article was a drug not designated solely by a name recognized in an official compendium, and it was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each ingredient; Section 502(f), the labeling of the article failed to bear (1) adequate directions for use; and (2) adequate warnings against use in those pathological conditions where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 502(j), the article was dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in its labeling; and Section 503(b) (4), the article was a drug subject to Section 503(b) (1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

*New drug violation*, Section 505(a), the article was a new drug within the meaning of Section 201(p), which was introduced into interstate commerce, and an application filed pursuant to Section 505(b) was not effective with respect to such drug.

DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED  
ACCORDING TO DIRECTIONS

DRUG FOR HUMAN USE

5981. **Alcorem.** (F.D.C. No. 41476. S. Nos. 13-268/9 P.)

**QUANTITY:** 260 btl. of fluid extract of ipecac root and 264 kits, each containing 1 btl. of fluid extract of ipecac root and 1 btl. of vitamin capsules at Chicago, Ill., in possession of Midwest Health Aids.

**SHIPPED:** (Fluid extract of ipecac root), 9-11-57 and 2-12-58, from New York, N.Y., and (vitamin capsules), from Chicago, Ill., on an unknown date.

**LABEL IN PART:** (Kit) "Alcorem Kit \* \* \* Contains bottle of Alcorem with dispenser, 21 Pinkies for Vitamin Deficiency, Weight Chart and Complete Instructions for home use," (btl.) "½ Ounce ALCOREM Emetic Brand of Fluid Extract of Ipecac - Alcohol 30%" and "21 Capsules Special PINKIES Capsules Natural Fortified Vitamin B Complex \* \* \* Each Capsule Contains: Vitamin B-1 1,000 U.S.P. Units Vitamin B-2 3,000 Micrograms Vitamin B-6 125 Micrograms Calcium Pantothenate 3,000 Micrograms Niacin Amide 10,000 Micrograms."

**ACCOMPANYING LABELING:** Circulars entitled "Instructions For the Use of Alcorem for the Relief of Drunkenness," "Alcorem Weight Chart for Men and Women," "Housewife Praises Pinkies," "Important Read Carefully," "Special Quick Action Order Blank," and "Live Longer."

**RESULTS OF INVESTIGATION:** The fluid extract and the capsules had been repackaged into kits by the dealer from bulk stock which had been shipped as described above. The circulars were printed locally on order of the dealer.

**LIBELED:** 3-19-58, N. Dist. Ill.; amended libel 5-27-58.

**CHARGE:** 502(a)—while held for sale, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for drunkenness; 502(j)—the article was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling; and 503(b)(4)—the article was a drug to which 503(b)(1) applied, and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

**DISPOSITION:** 10-1-59. Default—destruction.

#### DRUG FOR VETERINARY USE

**5982. Giles veterinary medicine.** (F.D.C. No. 43171. S. Nos. 58-465/6 P.)

**QUANTITY:** 4 1-gal. cans and 4 1-qt. btls. at Denver Colo.

**SHIPPED:** (Cans) 5-5-58, and (btls.), some time prior to 1955, from Oak Park, Ill., by Giles Remedy Co.

**LABEL IN PART:** (Can and btl.) "The Great 'Giles' Veterinary Medicine Oleum Lini-Aether Sulphuricus Ten Per Cent — Camphora \* \* \* A Veterinary Compound for Internal and External Use \* \* \* prepared for Horses and Cattle \* \* \* Made only by Giles Remedy Co. of Illinois."

**RESULTS OF INVESTIGATION:** Examination showed that the article was a yellow-colored, oily liquid, having odors of ether, camphor, and linseed oil.

**LIBELED:** 6-10-59, Dist. Colo.

**CHARGE:** 502(a)—the label of the article contained false and misleading representations and suggestions that the article was an adequate and effective treatment in horses and cattle for preventing or correcting "layups," loss of appetite and stamina, chills, colds, colic, and bloat, and for preventing and relieving shipping fever, and ailments caused by exposure; 502(e)(2)—the label of the article failed to bear the common or usual name of each of the active ingredients contained therein; 502(f)(2)—the labeling of the article failed to bear adequate warnings against use where its use may be dangerous to health and against unsafe dosage and methods and duration of administration or application; and 502(j)—the article was dangerous to health when used in the eyes, and internally, as directed in its labeling.

**DISPOSITION:** 7-22-59. Default—destruction.

#### NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

**5983. Bee Royale Capsules.** (F.D.C. No. 39873. S. No. 50-245 M.)

**QUANTITY:** 42 jars at Cambridge, Mass., in possession of Nature Food Centres, Inc.

**SHIPPED:** 1-23-57, from New York, N.Y.

**LABEL IN PART:** "Bee Royale Capsules \* \* \* Contents 30 Capsules Each Capsule Contains: Royal Jelly 5 mg. Thiamine Hcl 10 mg. Pyridoxin 0.5 mg. Nucleic Acid 2 mg. \*Calcium Pantothenate 10 mg. \*Biotin 0.5 mcg. Directions: Adults: One Capsule daily with principal meal."

**LIBELED:** 2-13-57, Dist. Mass.; amended libel 4-10-57.

**CHARGE:** 502(f)(1)—while held for sale, the labeling of the article failed to bear adequate directions for use for delaying old age, restoring sexual vigor, rejuvenating impaired glands, restoring vigor, eliminating a chronic feeling of tiredness, growing hair, restoring youthful sex functions to women in meno-



pause, producing a general state of well being, acting as a "fountain-of-youth cocktail," and overcoming neurasthenia, which were the conditions and purposes for which the article was offered in the leaflet entitled "Have you read these headlines" disseminated by, and on behalf of, the consignee, Nature Food Centres, Inc., Cambridge, Mass.; and 505(a)—the article was a new drug which may not be introduced into interstate commerce, and an application filed pursuant to law was not effective with respect to such drug.

**DISPOSITION:** Bee Royale, Inc., New York, N.Y., appeared as claimant and filed an answer denying that the article was misbranded as alleged in the libel. On 12-3-57, pursuant to stipulation of the parties the case was transferred to the United States District Court for the District of New Jersey. Interrogatories were then prepared and served upon the claimant by the Government. Thereafter, the claimant filed a motion for dismissal of the libel and for summary judgment. After consideration of the briefs and arguments of counsel, the court, on 4-11-58, handed down the following opinion in respect to the denial of claimant's motion (160 F. Supp. 818):

**HARTSHORNE, District Judge:** "Under the provisions of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 344(a),<sup>1</sup> the libellant seized 42 jars of what are called 'Bee Royale Capsules,' as a drug which was misbranded, while held for sale after shipment in interstate commerce, within the meaning of the statute (21 U.S.C. § 352(f)(1)),<sup>2</sup> in that its labeling did not set forth the claimed conditions for the cure of which the product was purportedly sold, as it should have done, *U.S. v. El Rancho Adolphus Products*, 140 F. Supp. 645, 648 (M.D.Pa. 1956), affirmed sub. nom. *U.S. v. Hohensee*, 243 F. 2d 367, 370 (3rd Cir. 1957); *Irons v. U.S.*, 244 F. 2d 34 (1st Cir. 1957); and also in that the said product was a 'new drug' within the meaning of the statute, 21 U.S.C. § 321(p)(1), as to which no effective application had been filed previously, as required by the statute.<sup>3</sup>

"While the libel was filed and the seizure occurred in the District of Massachusetts, the case was removed by order to this Court for trial, 21 U.S.C. § 334(a). Bee Royale, Inc., a New York corporation, appeared here as owner and claimant, filed answer, and now moves to dismiss the libel and for summary judgment under the Rules, F.R.C.P. 12(b), 56(b).

"The sole basis upon which the claimant makes such motion is that, subsequent to the above seizure, proceedings were instituted by the Post Office Department, not against this claimant but against Nature Food Centres, involving its selling Bee Royale Capsules through the mails. These proceedings were on the ground that such sale was 'a scheme for obtaining money through the mails by means of false and fraudulent pretenses \* \* \*', in violation of 39 U.S.C. § 259 and § 732. Bee Royale, Inc. claims that these subsequent Post Office proceedings had meanwhile been adjudicated in its favor, so that the Government is now estopped to claim that these similar drugs violate either of the above provisions of the Federal Food, Drug and Cosmetic Act, primarily on the theory of *res judicata*, as applied in the recent case of *U.S. v. R.C.A. and National Broadcasting Company*, 158 F. Supp. 333 (E.D.Pa. 1958). We turn to the legal principles there involved.

"It is elemental that to constitute *res judicata* there must have been, prior to the instant suit (1) and adjudication (2) of the same issues here involved (3) between the same parties or their privies. *U.S. v. International Building Co.*, 345 U.S. 502, 504 (1952); *Lawlor v. National Screen Service*, 349 U.S. 322,

<sup>1</sup> "Any article of food, drug, device, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce or while held for sale (whether or not the first sale) after shipment in interstate commerce, or which may not, under the provisions of section 344 or 355, be introduced into interstate commerce, shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found \* \* \*"

<sup>2</sup> "A drug or device shall be deemed to be misbranded \* \* \* (f) Unless its labeling bears (1) adequate directions for use; \* \* \*"

<sup>3</sup> 21 U.S.C. § 355 "(a) No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an application filed pursuant to subsection (b) is effective with respect to such drug."



326 (1955). Nor does the theory of collateral estoppel apply, save as to issues "actually litigated and determined in the prior suit." *Lawlor, supra*.

"But here none of these essential elements appears. (1) There has been no prior adjudication; (2) the issues 'adjusted,' not adjudicated, in the Post Office Department proceeding, are not the same as those here involved; (3) while the U.S. is the moving party in both proceedings, no privity has been shown to exist between Bee Royale, Inc. and Nature Food Centres.

"Not only so, but if Bee Royale, Inc. and Nature Food Centres are per-chance privy, then the present claimant is privy to an agreement with the Post Office Department that such proceedings 'will not act as a defense or relieve the undersigned of responsibility for violation of any other statute' than the above mailing statute. See 'Affidavit of Agreement' annexed to the present motion papers as Exhibit B.<sup>4</sup>

"That this 'Affidavit of Agreement,' the final act of the parties in the above Post Office proceedings, was not an adjudication of any res but a mere 'settlement' or 'adjustment' of the controversy between the Post Office Department and Nature Food Centres, as authorized by the Federal Administrative Procedure Act, Title 5, Executive Departments, § 1004(b),<sup>5</sup> is clear from its terms.

"In the next place, the issues in these Post Office proceedings differ from those involved in the present libel. The gist of the Government's charge in the Post Office Department proceedings was that the shipper of the capsules made specific and fraudulent representations as to the marvelous cures the capsules would achieve. These proceedings connoted a charge of intentional fraud. *Reilly v. Pinkus*, 338 U.S. 269 (1949); *Pinkus v. Reilly*, 157 F. Supp. 548 (D.N.J. 1957). On the contrary, the present libel does not charge a false representation, let alone one involving actual fraud. It charges a *failure to represent*, i.e., to state on the labeling of the capsules the ailments or conditions for the cure of which they were to be used by the public. Clearly this is a different issue than that presented in the Post Office Department proceedings, quite regardless of the lack of an adjudication there. Similar is the difference between the above Post Office proceedings and the other charge here made that the capsules are a 'new drug,' as to which the claimant has not proceeded as required by the statute.

"\* \* \* With a view to obviating the necessity for further proceedings herein, it is voluntarily agreed:

"That in any future mail order operation of the enterprise involved in this proceeding, affiant will not represent or make any claims for the preparation being sold in said enterprise that: 1. It will 'rejuvenate failing or worn-out glandular activities in human beings'; 2. It constitutes 'a fountain of youth' and a 'restorer of sexual vigor,' or that it will restore sexual vitality to impotent persons; 3. It will grow hair on bald heads or where the hair is thinning; 4. It will restore youthful sex functions to women in menopause; 5. It will insure good health to users.

"That the acceptance of this affidavit by the Assistant General Counsel, Fraud and Mailability Division, of the Post Office Department, as a basis for disposing of the pending charges now involved herein shall not be construed as an approval of any business which the said affiant has conducted or may hereafter conduct under the name aforesaid set forth in the caption hereof, or any other name or names;

"It is further agreed that if the Post Office Department receives evidence showing the resumption of the enterprise as herein agreed to be discontinued, in violation of the terms of this affidavit, the Assistant General Counsel, Fraud and Mailability Division, Post Office Department, may issue or cause to be issued to affiant a ten (10) days' notice for a hearing to determine whether a violation of the said affidavit has been made and that in the event of any affirmative determination of that issue, a fraud order may issue forthwith against any name or names then employed by affiant in the operation of the said mail order enterprise;

"Affiant understands that this affidavit relates exclusively to the proceedings specified in the caption hereof and its filing will not act as a defense or relieve the undersigned of responsibility for violation of any other statute, but the filing shall not be construed as a confession that the said instant statutes or any other statute has been violated;

"The undersigned, upon acceptance of this affidavit by the Assistant General Counsel, Fraud and Mailability Division of the Post Office Department, as a basis for disposing of the pending charges, waives all rights to any present or future indemnity covering insured or c.o.d. shipments of the merchandise sold under the above names and involved in this proceeding, and agrees that any such claim may be forthwith disallowed by the Post Office Department."

"(b) The agency shall afford all interested parties opportunity for (1) the submission and consideration of facts, arguments, offers of settlement, or proposals of adjustment where time, the nature of the proceeding, and the public interest permit, and (2) to the extent that the parties are unable so to determine any controversy by consent, hearing, and decision upon notice and in conformity with sections 1006 and 1007 of this title." (Title 5, Executive Departments, § 1004(b).)

"Nor is the decision of *U.S. v. R.C.A., supra*, at all to the contrary. There the court was passing on the validity of an agreement between the National Broadcasting Company and the Westinghouse Broadcasting Company in exchanging between themselves two television and radio stations. This transaction had been specifically approved by the Federal Communications Commission. Thereafter the Government brought the instant proceedings to adjudge this exchange agreement to be in violation of the Sherman Act. The court held in the above case:

There is no doubt that in finding that the exchange was in the public interest, it [the Federal Communications Commission] necessarily decided \* \* \* that the exchange did not involve a violation of a law [the Sherman Act] which declares and implements a basic economic policy of the United States. 158 F. Supp. at 336.

In other words, the court found that the first adjudication did involve the very issue which the Government later sought to raise.

"Claimant also argues double jeopardy. But this argument, as well, is insubstantial, both because of the difference in issues, and because of the basic principle that double jeopardy applies only to criminal proceedings. The libel proceedings here are civil.

"An order may be entered dismissing the above motion."

On 4-25-58, the claimant filed an objection to answering the Government's interrogatories based on the ground that to answer such interrogatories would violate the privilege against self-incrimination of the corporation or its officers and agents. On 6-11-58, the court handed down the following opinion relating to the claimant's objection (132 F. Supp. 944):

HARTSHORNE, *District Judge*: "Libellant, United States Government, has seized a quantity of 'Bee Royale' capsules, under the provisions of the Federal Food, Drug and Cosmetic Act, 21 U.S.C.A. § 334(a), as having been misbranded. It also claims that the said product was a 'new drug' within the meaning of the statute, 21 U.S.C.A. § 321(p) (1), as to which statutory conditions precedent had not been taken by their producers and owners. Bee Royale, Inc., a New York corporation, now appears as owner and claimant and, after its application for summary judgment was denied herein,<sup>1</sup> filed objections to a series of interrogatories asked of it as discovery, by libellant. The point presently raised by claimant against these interrogatories is that they deny it the constitutional privilege of freedom from self-incrimination. U.S. Const. Amendment V.

"However, it will be noted that claimant is not an individual but a corporation. It has long been the established law that a corporation cannot claim the privilege of freedom from self-incrimination. This is because this constitutional privilege was designed to protect a natural person from being condemned out of his own mouth by governmental compulsion, torture, star chamber proceedings, and the like, as practiced in England before the American Revolution. Therefore this privilege did not apply to a mere artificial person, created by the State, to enable that person to set at naught its obligations to its creator, *Hale v. Henkel*, 1906, 201 U.S. 43, 26 S. Ct. 370, 50 L. Ed. 652; *United States v. White*, 1944, 322 U.S. 694, 64 S. Ct. 1248, 88 L. Ed. 1542; *Oklahoma Press Pub. Co. v. Walling*, 1946, 327 U.S. 186, 66 S. Ct. 494, 90 L. Ed. 614; *Curcio v. U.S.*, 1957, 354 U.S. 118, 77 S. Ct. 1145, 1 L. Ed. 2d 1225. Furthermore, this privilege of freedom from self-incrimination is a purely personal one, which can be claimed only by the person who is sought to be incriminated, and not by him on behalf of third parties, *Rogers v. U.S.*, 1951, 340 U.S. 367, 71 S. Ct. 438, 95 L. Ed. 344.

"It will further be noted that the sole party that is called on to answer these interrogatories under the Rules is this same corporation, the claimant. Thus, assuming that the duty of this corporation to answer these interrogatories amounts to a compulsion similar to that of a subpoena, *Bowles v. Trow-*

<sup>1</sup> See this Court's opinion. *United States v. 42 Jars \* \* \** "*Bee Royale Capsules \* \* \**," D.C.N.J., 160 F. Supp. 818.



bridge, D.C. Cal. 1945, 60 F. Supp. 48, it is quite clear that this party, solely under compulsion, has no right to plead this privilege.

"True it is that the answer of this corporation to this interrogatory must be sworn to by some individual, who is its 'officer or agent, who shall furnish such information as is available to the party.' F.R.C.P. 33, 28 U.S.C.A. Of course, if any such officer or agent, who is directed by the corporation to make these answers, can establish that such answers will incriminate him, he can refuse to answer them, because of his right to avail himself of the aforesaid privilege. *United States v. White*, supra. But if the corporation select such a person to answer these interrogatories, and, because of his pleading this privilege, these interrogatories are therefore not answered, the corporation itself will be in default, for not making the requisite discovery under the Rules. It will thus be the clear duty of the corporation to select an officer or agent for the above purpose, who will not have personally participated in anywise in any such questionable transaction, and who thus cannot be incriminated by such answers. This the corporation can easily do under its broad corporate powers, using even its attorney, for instance, whose duty it would then be to 'furnish such information as is available to the party'—the sum total of the corporate information. 2 Barron & Holtzoff, Fed. Practice & Procedure, § 774; 4 Moore, Fed. Practice, 2nd ed., § 33.07; *Holler v. General Motors Corp.* D.C.E.D. Mo. 1944, 3 F.R.D. 296; *Societe Internationale etc. v. McGranery*, D.C.D.C. 1953, 14 F.R.D. 44, 50.

"Nor is this officer or agent, appointed by the corporation for that purpose, then acting as an individual, under compulsion of the Government or of this Court. The interrogatories are addressed not to him but to the corporation. He answers solely because of his undertaking so to do at the sole instance of the corporation. He is free to refuse the request of his employer, the corporation, in that regard. But, of course, if he refuses such corporate request, that leaves the corporation in default as to its duty to make discovery, and subject to the sanctions provided by the Rules in such event. F.R.C.P. 37.

"Nor, when such an officer or agent of the corporation, who will not be incriminated by making that discovery on behalf of the corporation, makes such discovery, can he claim the privilege from self-incrimination, because of the fact that such discovery may indicate that some other officer or agent of the corporation has participated in such questionable transaction. This is because, as stated above, this privilege is a purely personal one.

"It therefore follows that since (1) this corporation can appoint some officer or agent to answer interrogatories for it, who will not be personally incriminated by such answers, and since (2) the corporation itself cannot claim any privilege against self-incrimination, it has no right to plead that privilege, as an objection to answering the interrogatories here in question.

"Such objection will therefore be stricken on order."

On 6-16-58, an order was entered denying and overruling claimant's objections to the interrogatories. On 6-23-58, it appearing that the claimant was electing to stand on its self-incrimination objection by refusing to answer the interrogatories served upon it, the court granted a Government motion for a default decree and ordered that the article be condemned and destroyed. Claimant appealed to the United States Court of Appeals, and, on 3-12-59, the following opinion was handed down by that court affirming the judgment of the district court (264 F. 2d 666) :

GOODRICH, *Circuit Judge*: "This case deals with two points. One is the scope to be given to finality of administrative action. The other has to do with corporate answers to interrogatories under Rule 33.<sup>1</sup>

"The points come up in this fashion. In February, 1957, a libel was filed in the United States District Court in Massachusetts alleging that a drug called 'Bee Royale Capsules' was misbranded while being held for sale following interstate commerce shipment, in that its label did not bear adequate directions for use.<sup>2</sup> An amendment to the libel was filed in April adding the allega-

<sup>1</sup> Fed. R. Civ. P. 33.

<sup>2</sup> 21 U.S.C.A. § 352(f) (1) (Supp. 1958). Seizure and condemnation of the capsules was sought under 21 U.S.C.A. § 334 (Supp. 1958).



tion that the article was a 'new drug' which may not be introduced into interstate commerce without an effective application establishing its safety.<sup>3</sup> Bee Royale, Inc., a New York corporation, filed a claim of ownership in a Massachusetts action.

"In the meantime, in March, 1957, subsequent to the filing of the libel just described, the Post Office Department issued a fraud complaint against two companies called 'Nature Food Centres' and 'Nature Food Centres, Inc.' of Cambridge, Massachusetts. The charge was that these concerns were obtaining money through the mails by fraudulent representations of benefits to be had by taking Bee Royale Capsules.<sup>4</sup> The controversy with the Post Office Department was settled by an agreement on the part of the Nature Food Centres people to withdraw from its advertising several specified claims with regard to the beneficial effects of the capsules.<sup>5</sup> This settlement was in the form of an affidavit signed by Henry Rosenberger, owner of Nature Food Centres and Nature Food Centres, Inc. One paragraph of the affidavit stated that the signer 'understands that this affidavit relates exclusively to the proceedings specified \* \* \* and its filing will not act as a defense or relieve the undersigned of responsibility for violations of any other statute \* \* \*.' Thus ended, so far as we know, the controversy between Mr. Rosenberger's enterprises and the Post Office Department.

"In the meantime the Massachusetts case had been removed to the District of New Jersey under 21 U.S.C.A. § 334(a) (Supp. 1958). The claimant moved to dismiss the action basing its motion upon the Post Office's fraud complaint and subsequent settlement. This motion the trial court denied. 160 F. Supp. 813 (D.N.J. 1958). Written interrogatories, pursuant to Fed. R. Civ. P. 33, had been served on the claimant, Bee Royale, Inc., by the Government. The claimant objected to all the Government's interrogatories. The only objection now relevant is that of the Fifth Amendment. The district judge rejected the claimant's point that its refusal to answer the interrogatories was privileged under the Fifth Amendment. 162 F. Supp. 944 (D.N.J. 1958). Upon the further refusal of the claimant to answer the interrogatories he gave a default decree of condemnation under Fed. R. Civ. P. 37(d).

#### I. Res Administrata.

"Bee Royale, Inc., readily admits that the orthodox established doctrine of res judicata does not help it in this case. That admission is well founded. The parties were not the same in the Post Office proceeding as they are in this action for seizure. If there is any privity between Bee Royale, Inc. and Mr. Rosenberger's Nature Food Centres, that fact is not disclosed. Neither are the issues the same. The Post Office proceeding was based upon an alleged fraud as the section of the statute cited will show.<sup>6</sup> The condemnation action under the statute already cited is based on misbranding and does not require fraud.<sup>7</sup> Furthermore, there was no 'final adjudication' in any ordinary sense of that term in the Post Office proceeding. Mr. Rosenberger filed an affidavit and the charges made against his business concerns were ended so long as his promises were kept. Since there was neither privity of parties, identity of issues nor final adjudication there is not anything in the two proceedings that even faintly resembles the basis for res judicata. See Restatement, Judgments, § 1 (1942); Von-Moschzisker, Res Judicata, 38 Yale L.J. 299, 300 (1929).

<sup>3</sup> A "new drug" defined in 21 U.S.C.A. § 321(p) (Supp. 1958), cannot lawfully be introduced into interstate commerce unless an application designed to establish its safety is "effective" with respect to the drug. 21 U.S.C.A. § 355 (Supp. 1958). Violation of this section subjects the drug to condemnation under section 334.

<sup>4</sup> This action was based upon 39 U.S.C.A. §§ 259, 732 (1928).

<sup>5</sup> The claims agreed to be withdrawn were that:

"1. it will rejuvenate failing or worn-out glandular activities in human beings";  
 "2. it constitutes 'a fountain of youth' and a 'restorer of sexual vigor,' or that it will restore sexual vitality to impotent persons;  
 "3. it will grow hair on bald heads or where the hair is thinning;  
 "4. it will restore youthful sex functions to women in menopause;  
 "5. it will insure good health to users."

<sup>6</sup> See note 4, *supra*.

<sup>7</sup> *United States v. Dotterweich*, 320 U.S. 277, 281 (1943); *Alberty Food Products v. United States*, 194 F. 2d 463, 464 (9th Cir. 1952).

"The common element in the two proceedings has to do with the claim of alleged benefits to be derived from the consumption of Bee Royale Capsules. Based upon this common factor the appellant urges us that the court should create a doctrine known as 'res administrata.' It points out the confusion which may be created in the mind of a citizen by finishing up one matter with one department of Government and then finding that he is not out of difficulty with another department. So the suggestion is that by the adoption of the proposed rule of 'res administrata' the right hand of Government will be conclusively presumed to know what its left hand has done. An adjudication, or a settlement, or a ruling or whatever by one administrative agency will end all matters relating to that general question, whatever other departments or statutes are involved.<sup>8</sup> We take it that this is to be the effect regardless of any privity of parties and regardless of departments, commissions or agencies involved. And perhaps regardless, too, of any consent given by a party in conflict with a Governmental agency that the settlement of his case is limited to that controversy only.<sup>9</sup> A benevolent Uncle Sam is, as the cartoons show him, to be treated as a unified individual with the addition of a degree of omniscience not accorded to him by anyone before. Furthermore, all his citizens, both natural and corporate, are included in the family of his children thus to create privity, or something akin to it, between them.

"It is hardly necessary to add that a court cannot swallow any such broad proposition as this. Yet such a broad assertion would be necessary if the appellant were to get any help here.

"That the administrative process has created difficulties for citizens in their relation to Government is a truism.<sup>10</sup> The judicial control of agency action was a subject of thoughtful consideration for a long time both by the Congress and the American Bar Association. This consideration resulted in the Administrative Procedure Act of 1946, 5 U.S.C.A. §§ 1001-11 (Cum. Supp. 1949), and gave a standard for court supervision of administrative action. There is a growing recognition of the doctrine of *res judicata* as applied to action by administrative tribunals.<sup>11</sup> It takes fifty-one pages in Professor Davis' book on administrative law to discuss it.<sup>12</sup> We shall, no doubt, have growth in this area. But the growth will come step by step; at least it will if courts are to be in charge of it.

"Furthermore, while there may be cases where the administrative process works hardship, this is not one of them. As indicated above, there is not a single fibril to connect these two pieces of Government procedure except certain claims made on behalf of that product known as Bee Royale jelly.<sup>13</sup>

## II. The Unanswered Interrogatories.

"We think it clear that if Judge Hartshorne was correct in overruling the claimant's appeal to the Fifth Amendment as a protection against answering the interrogatories that the imposition of the judgment against it was within the court's discretion. Fed. R. Civ. P. 37(d).<sup>14</sup>

<sup>8</sup> But cf. *United States v. Radio Corp. of America*,—U.S.—(Feb. 24, 1959), reversing 158 F. Supp. 533 (E.D. Pa. 1958).

<sup>9</sup> Appellant says that the agreement between the Post Office Department and the Nature Food Centres people is binding on other executive agencies of Government. But appellant evidently asserts that it should not be bound by the agreement, or at least that portion of it which waives the agreement as a defense to violations of other statutes. According to appellant, privity is a one way street.

<sup>10</sup> E. G., see the Hoover Commission *Task Force Report on Regulatory Commissions* (1949); *Jackson, The Supreme Court in the American System of Government*, 50. 51 (1955). See also with a happier but nonetheless pungent approach *Parkinson, Parkinson's Law* (1957).

<sup>11</sup> Compare *United States v. Five Cases . . . of Capon Springs Water*, 156 F. 2d 493 (2d Cir. 1946), with *United States v. Willard Tablet Co.*, 141 F. 2d 141 (7th Cir. 1944). Both of these cases are clearly distinguishable from the case at bar. See also Kleinfeld and Goding, *Res Judicata and Two Coordinate Federal Agencies*, 95 U. Pa. L. Rev. 388 (1947); *Davis, Administrative Law* 579-80 (1951).

<sup>12</sup> *Davis, Administrative Law* 563-613 (1951). Other references are listed in *Gellhorn and Byse, Administrative Law* 1183. n. 1 (1954).

<sup>13</sup> See *United States v. 3963 bottles, etc.*—F. Supp.—(E.D. Ill. Sept. 8, 1958).

<sup>14</sup> In *Societe Internationale v. Rogers*, 357 U.S. 197 (1958), the Supreme Court modified district court action taken under Rule 37(b). That case was one of extreme hardship because the plaintiff had done all in its power to obey the court order but was frustrated in its efforts to comply completely since Swiss law prevented it from doing so.



"Bee Royale, Inc. does not claim that it, as a corporation, can raise the question of the constitutional provision of freedom from disclosure as applied to it. Its argument concedes that the corporation itself may not claim the Fifth Amendment. *United States v. White*, 322 U.S. 694 (1944); *Wilson v. United States*, 221 U.S. 361 (1911).

"The argument has a further basis, however. It says that answers by a corporation to interrogatories addressed to it must, obviously, be made by some human being on its behalf. Now if the corporate officer who gives the answers, on behalf of the corporation, states things that may involve criminal responsibility, he may find himself involved in a criminal prosecution, especially since liability of corporate officers under the food and drug act is one at peril and no mens rea is involved. See *United States v. Dotterweich*, 320 U.S. 377 (1943). But personal criminal liability was the very point involved in the *White* case, *supra*.

"This argument would present more possibilities for hardship if the questions were to be answered only by an officer who would be competent to testify on the corporation's behalf, as was the rule prior to the 1948 amendment. See 4 Moore, Federal Practice § 33.07 (2d ed. 1950). Under the amended rule the agent who answers on behalf of the corporation does not need to have personal knowledge. The corporation's attorney will do. 4 Moore, Federal Practice § 33.07 (2d ed. 1950).

"But we are getting into unnecessary difficulties here. The Fifth Amendment plea is a personal one and a corporation cannot take advantage of it. That is really all that is involved as this case came to the district court and as it comes to us. Accord: *United States v. 48 Jars* etc. — F. Supp. — (D.D.C. Nov. 14, 1958).

"The judgment of the district court will be affirmed."

5984. Vitamin B<sub>12</sub> injection. (F.D.C. No. 41285. S. No. 79-243 M.)

QUANTITY: 991 packaged vials at Brooklyn, N.Y.

SHIPPED: 11-13-57, from Chicago, Ill., by Hallmark Laboratories, Inc.

LABEL IN PART: (Vial) "10 cc Vial \* \* \* Vitamin B<sub>12</sub> Crystalline U.S.P. 1000 Micrograms per cc in Isotonic Sod. Chloride Soln. with 2% Benzyl Alcohol Intramuscular-Intravenous \* \* \* 051177."

RESULTS OF INVESTIGATION: Examination showed that each cubic centimeter of the article contained 995 micrograms of cyanocobalamin (vitamin B<sub>12</sub>), 8.96 milligrams of sodium chloride, and a substantial amount of unidentified dissolved material.

LIBELED: 12-18-57, E. Dist. N.Y.

CHARGE: 501(b)—when shipped, the quality and purity of the article fell below the standard for *cyanocobalamin injection* set forth in the United States Pharmacopeia since it contained a substantial amount of unidentified dissolved material which is not permitted by the standard as an ingredient of *cyanocobalamin injection*; and 505(a)—the article, because of the presence of unidentified dissolved material, was a new drug within the meaning of the law, and an application filed pursuant to the law was not effective with respect to such drug.

DISPOSITION: 4-29-59. Consent—destruction.

#### DRUG FOR VETERINARY USE

5985. Cardiobee 15 Injection and Pangamic Acid (B-15) capsules. (F.D.C. No. 42313. S. Nos. 1-412 P, 2-316 P.)

QUANTITY: 584 cartoned vials of *Cardiobee 15 Injection* and 1 vial of *Pangamic Acid capsules* at Hialeah, Fla.

SHIPPED: Between 4-17-58 and 8-6-58, from San Francisco, Calif., by John Beard Memorial Foundation.



**LABEL IN PART:** (Vial and carton) "10 cc Multiple Dose Sterile Vial Car-diobee 15 Injection Each cc contains 100 mg. of Na-Glucono-di (N-Diisopropyl-amino) Acetate, Benzyl Alcohol 2% Physiological Saline Solution q.s. For Veterinary Use Only Dist. by Zirin Enterprises Hialeah, Florida" and (vial) "Blue \* \* \* Gold B-15 Capsules each capsule contains 50 mg. Pangamic Acid (Vitamin B-15) Na-Glucono-di (N-diisopropylamino) acetate."

**LIBELED:** 12-4-58, S. Dist. Fla.

**CHARGE:** 505(a)—the articles were new drugs which may not be introduced into interstate commerce since an application filed pursuant to law was not effective with respect to such drugs.

**DISPOSITION:** 8-4-59. Default—destruction.

### DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

5986. Pituitary anterior solution. (F.D.C. No. 42984. S. No. 28-499 P.)

**QUANTITY:** 75 ctnd. vials at Houston, Tex.

**SHIPPED:** 1-27-59, from Philadelphia, Pa., by Vitamix Corp.

**LABEL IN PART:** (Vial and ctn.) "30 cc. Multiple Dose Vial Vitopit \* \* \* Intramuscular Only \* \* \* Distributed by Coastal Medical Supply Co. Hous-ton, Texas Each cc. Represents The Water Soluble Extraction of Dried Glands Derived From: Anterior Pituitary, Fresh Gland \* \* \* 10½ Grs. Ovarian Whole Gland, Fresh Gland \* \* \* 40 Grs. Procaine HCL \* \* \* 1% Chlorobutanol (Chloral Deriv.) 0.5% Contains No Recognized Therapeuti-cally Active Ingredients. Indications: Non-Specific Protein Therapy."

**LIBELED:** 4-15-59, S. Dist. Tex.

**CHARGE:** 502(a)—when shipped, the label statement "Indications: Non-spe-cific Protein Therapy" was false and misleading as applied to an article which is not an adequate and effective protein therapy treatment; and 502(f) (1)—the label of the article failed to bear adequate directions for use since no adequate directions could be written as the article was without therapeutic value.

**DISPOSITION:** 6-1-59. Default—destruction.

5987. Nutri-Bio Food Supplement. (F.D.C. No. 43216. S. No. 51-962 P.)

**INFORMATION FILED:** 8-5-59, Dist. Minn., against Gordon R. Cook, t/a Nutri-Bio Products, Brainerd, Minn.

**ALLEGED VIOLATION:** On 2-16-59, while the article was being held for sale by the defendant after shipment in interstate commerce, the defendant caused oral representations to be made in the course of a sales talk holding the article out as an effective treatment for various diseases, symptoms, and conditions as hereinafter described, which act resulted in the article being misbranded.

**LABEL IN PART:** (Ctn.) "NUTRI-BIO food supplement natural or organic VITAMINS AND MINERALS Suggested Daily Portions As a Dietary Sup-plement 364 Mineral Tablets 182 Vitamin Tablets."

**CHARGE:** 502(f) (1)—the labeling of the article failed to bear adequate direc-tions for use in the treatment of the diseases, symptoms, and conditions for which the article was intended, namely, sinusitis, nervous indigestion, arthri-tis, swelling of joints, rheumatism, reducing, overeating, hunger, gaining weight, nervousness, nervous breakdown, inadequate assimilation of food, blood clot, cavities in teeth, diarrhea of infants, ulcers, stomach flu, lack of

balance of the stomach, gallstones, kidney stones, bleeding ulcers, balancing the acids of the stomach, irritation of the stomach, tiredness, rundown condition, colds and other respiratory ailments, heart attacks, heart trouble, strokes, hardening of the arteries, and improper circulation of the blood, which were the diseases, symptoms, and conditions for which the article was held out by the defendant in the course of the above-mentioned sales talk.

**PLEA:** Guilty.

**DISPOSITION:** 9-4-59. The defendant was sentenced to the custody of the United States Marshal for one hour and fined \$100.

### DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

**5988. Methrodyne tablets.** (F.D.C. No. 42859. S. No. 47-822 P.)

**QUANTITY:** 84 ctns., 12 btls. each, and 9 btls., at Hartford, Conn.

**SHIPPED:** In 1952, from Newark, N.J., by Chase Chemical Co.

**LABEL IN PART:** (Btl.) "Metrodyne \* \* \* Anodyne-Antipyretic Distributed by Metro Products, Inc., Hartford, Connecticut \* \* \* Each tablet contains: Acetylsalicylic Acid 3 grains Acetophenetidin 2 grains Aluminum Hydroxide, Magnesium Carbonate present as buffer substances."

**RESULTS OF INVESTIGATION:** Examination showed that each tablet of the article contained 55 percent of the labeled amount of aspirin (acetylsalicylic acid) and the aspirin in the article was undergoing decomposition.

**LIBELED:** 3-12-59, Dist. Conn.

**CHARGE:** 501(c)—while held for sale, the quality of the article fell below that which it was represented to possess; and 502(a)—the label statement "Each Tablet Contains \* \* \* Acetylsalicylic Acid 3 grains" was false and misleading as applied to a product which contained less than 3 grains of aspirin; and 502(a)—when shipped, the label statement "To be dispensed only by or on the prescription of a physician" was false and misleading as applied to a product not restricted to prescription sale; and 502(e) (2)—the label of the article failed to bear the common or usual name of the active ingredient, aspirin.

**DISPOSITION:** 6-20-59. Default—destruction.

**5989. HOC Hangover capsules.** (F.D.C. No. 43307. S. No. 53-546 P.)

**QUANTITY:** 1 drum of 20,000 capsules, and 1,600 plastic boxes, 3 capsules each, at Los Angeles, Calif., in possession of HOC Laboratories, Inc.

**SHIPPED:** The article was shipped in bulk, between 5-5-59 and 5-20-59, from Inwood, Long Island, N.Y.

**LABEL IN PART:** (Drum insert label) "Kuvet Capsule Formula \* \* \* Each Capsule Contains: \* \* \* Yeast Protein Enzymatic Hydrolysate 2 gr. Alfalfa Lvs. Po. 2 gr. Vitamin B-1 (Thiamin Chloride) 1 mg. \* \* \* Vitamin B-2 (Riboflavin) 1.5 mg. \* \* \* Ascorbic Acid (as sodium ascorbate) 30 mg. Magnesium Trisilicate 3 gr. Chlorophyllins 5 mg."; (insert label of boxes) "A Product of HOC Laboratories, Inc., Los Angeles, Calif. HOC Hang-Over Capsules Directions and Ingredients: Each Capsule Contains: (a) Vitamin B<sub>1</sub> (Thiamine HCl) 100% minimum adult daily requirement Vitamin B<sub>2</sub> Riboflavin) 125% minimum adult daily requirement Vitamin C (Ascorbic Acid) 100% minimum adult daily requirement A scientific blended base of High Potency Yeast Protein Enzymatic Hydrolysate, Alfalfa and Chlorophyllins."

**ACCOMPANYING LABELING:** Display cards for retail packages bearing the words "H.O.C. Capsules Overindulgence," and a number of loose box labels.

RESULTS OF INVESTIGATION: The article in the boxes was repacked from bulk stock shipped as described above.

LIBELED: 7-22-59, S. Dist. Calif.

CHARGE: 501(c)—while held for sale, the strength of the article differed from that which it was represented to possess, namely, ascorbic acid (drum label) 30 milligrams, and (box label) 100% minimum daily requirement in each capsule; 502(a)—the label statements (bulk drum) "Each capsule contains \* \* \* ascorbic acid (as sodium ascorbate) 30 mg." and (box label) "Each capsule contains \* \* \* Vitamin C (ascorbic acid) 100% minimum daily requirement" were false and misleading as applied to a product which contained little if any ascorbic acid; and the box label of the article contained false and misleading representations that the article was adequate and effective to prevent and to stop hangover and to restore perfect balance to the system.

DISPOSITION: 9-16-59 and 9-22-59. Default—delivered to the Food and Drug Administration.

### DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

#### DRUGS FOR HUMAN USE

5990. Cernelle Pollen tablets. (F.D.C. No. 42893. S. No. 40-252 P.)

QUANTITY: 210 100-tablet btls. at San Francisco, Calif.

SHIPPED: 8-29-58, from Winter Park, Fla., by Cernelle Pollen Co.

LABEL IN PART: (Btl.) "A Concentrated Food Cernelle Pollen Tablets Imported from Sweden Pure Special Treated Pollen High in Amino Acids, Natural Vitamins and Minerals \* \* \* 1-3 Tablets daily \* \* \* Cernelle Pollen Co. Winter Park, Florida"; (btl. top) "Cernelle Pollen Vegeholm Sweden."

ACCOMPANYING LABELING: Circulars entitled "Cernelle Pollen Tablets."

LIBELED: 3-24-59, N. Dist. Calif.

CHARGE: 502(a)—when shipped and while held for sale, the labeling accompanying the article contained false and misleading representations that the article was an adequate and effective treatment to maintain general well-being; to delay the arrival of old age and to keep the body young and virile; to prevent diseases; to purify the blood; and that the article was effective as a laxative and rejuvenator; to develop sound muscles, bones, blood and glands; to better body functions, to produce uncommon vitality; and to cure cancer.

The libel also charged that the article was misbranded under the provisions of the law applicable to foods as reported in notices of judgment on foods.

DISPOSITION: 5-5-59. Default—destruction.

5991. Mill Rue tonic. (F.D.C. No. 41641. S. No. 11-294 P.)

QUANTITY: 196 8-oz. btls. at Bluffton, Ind.

SHIPPED: On or about September, 1957, from Carlock, Ill., by Roy Paxton.

LABEL IN PART: "MILL RUE TONIC HEMATINIC STOMACHIC \* \* \* EACH FLUID OUNCE SUPPLIES \* \* \* MALLOW HERB \* \* \* 5.6 GM (60 GR.) FERRIC AMMONIUM CITRATE 4.95 GR. VITAMIN B<sub>1</sub> \* \* \* 5.69 MG VITAMIN B<sub>2</sub> \* \* \* 3.14 MG. NIACINAMIDE 6.0 MG."



ACCOMPANYING LABELING: Brochures entitled "Why Suffer, Take Mill Rue and Enjoy Life as You Live."

LIBELED: 3-28-58, N. Dist. Ind.

CHARGE: 502(a)—when shipped, the labeling accompanying the article contained false and misleading representations that the article was an adequate and effective treatment for cancer, ulcers, kidney and bladder troubles.

DISPOSITION: 6-12-58. Default—25 bottles of the article and 25 copies of the brochure were delivered to the Food and Drug Administration and the remainder of the article and the brochure were destroyed.

5992. Ketovite tablets and Bioplete tablets. (F.D.C. No. 43163. S. Nos. 53-058/9 P.)

QUANTITY: 20,000 tablets in bulk container, 28 100-tablet btl., 60 200-tablet btl., 72 400-tablet btl., and 6 1,000-tablet btl. of Ketovite; and 10,000 tablets in bulk container; 17 180-tablet btl., and 30 360-tablet btl. of Bioplete at Los Angeles, Calif., in possession of Professional Foods.

SHIPPED: 3-22-59 (Ketovite), and 4-1-59 (Bioplete), from Cedar Rapids, Iowa, by Professional Foods.

LABEL IN PART: (Btl.) "Ketovite \* \* \* A Dietary Supplement made from Liver and other Meats (dessicated), Milk Solids, Rice Bran, Wheat Germ, Fractions from Wheat Germ, Rice Bran and Soya Oils, Amino Acids, Extracted Proteins, Alfalfa and Cereal Grain Juice Concentrates, Diastase, Enzymes, Vitamins and Minerals from Food Sources. \* \* \* Distributed by Professional Foods, Cedar Rapids, Iowa," and "Bioplete A Dietary Supplement, made from Liver and other Meats (dessicated), Milk Solids, Rice Bran, Wheat Germ, Fractions from Wheat Germ, Rice Bran and Soya Oils, Amino Acids, Extracted Proteins, Alfalfa and Cereal Grain Juice Concentrates, Diastase, Enzymes, Vitamins and Minerals from Food Sources. \* \* \* Distributed by Micro-Nutrients, 219 2nd Ave., S.W., Cedar Rapids, Iowa."

ACCOMPANYING LABELING: (For Ketovite) booklets entitled "The Facts About a Four-Way Product!" and leaflets entitled "For Your Well Being!—Ketovite"; and (for Bioplete) booklets entitled "Why You Need More!" and leaflets entitled "For Your Well Being!—Bioplete"; and a number of loose labels for Ketovite and Bioplete.

RESULTS OF INVESTIGATION: The articles were shipped in bulk from Iowa and were repacked and relabeled by the dealer. Literature was sent from Iowa at the request of the dealer.

LIBELED: 6-2-59, S. Dist. Calif.

CHARGE: 502(a)—when shipped and while held for sale, the labeling of the articles contained false and misleading representations that the articles were adequate and effective for the treatment and prevention of common diseases due to a partial starvation even though regular, normal meals may be consumed; growing old; chronic fatigue; anxiety and worry; headaches, stomach upsets, insomnia, creaking and aching joints; body deterioration; debility and sickness; chronic sickness and organic degeneration; inadequate nerve function; lack of endocrine and enzyme output; improper teeth and bones; wearing out of the body; underdeveloped muscles of arms, legs, and heart; blocking of hormone formation of the anterior pituitary gland; insufficient insulin production; artery and heart disease; retarded mental development; cell starvation; lack of consciousness and vitality; arrested growth; collapse during hard work and worry of older people; failure to repair damaged parts

of the body; improper regulation of cholesterol; improper brain function; dementia; unhealthy eye structure and function; infection; scaly skin; defective tooth formation; paralysis; nerve degeneration; degeneration of the testes and female generative organs; respiratory and circulatory diseases; nerve degeneration which may affect walking and heart action; dropsy; heart sickness; hemorrhagic conditions; dermatitis; diarrhea; diphtheria; impaired response to the pituitary hormones; low blood pressure; digestive distress; numbness of the hands and feet; deleterious emotional changes; improper use and conversion of cholesterol; degeneration of the spinal cord; improper formation or use of life supporting hormones; improper function and maintenance of connective tissue; hemorrhages of the capillaries; arthritis; sterility; destruction of essential lipids of the body chemicals; muscular dystrophy; cardiac or heart tissue degeneration; serious disorders of the body; nutritional imbalance; deteriorating arteries, hearts, brains; defects of the eyes and urinary tracts and defective hearts and blood vessels of babies; tuberculosis and structural heart trouble of children; and that the articles would supply adequate and effective amounts of essential amino acids, essential lipids, and essential trace minerals; that sugar in the diet was used almost exclusively to furnish energy for brain cells; that inclusion of vitamin B<sub>12</sub> would increase the effects of adrenal hormones; that inclusion of choline would cause the liver to convert simple fats into phospholipids, and that inclusion of betaine would cause the body to have a reservoir of immediately available energy for muscles and nerves.

DISPOSITION: 6-24-59. Default—destruction.

5993. Vi-San Food Supplement. (F.D.C. No. 41513. S. Nos. 11-762 P, 11-769 P.)

QUANTITY: 11 pkgs., each containing 60 capsules, and 180 tablets, at Detroit, Mich.

SHIPPED: Between 1-13-58 and 3-25-58, from Burbank, Calif., by Vi-San Co.

LABEL IN PART: "Vi-San Food Supplement Therapeutic Nature's Organic Vitamins \* \* \* Minerals \* \* \* Exclusive SPECTRONIC (R) Concentrated Base."

ACCOMPANYING LABELING: Folders entitled "Why Millions of Americans," "Live Lively," "A Report On The Health of the Nation," and "Record O Gram"; leaflets entitled "Prescription for Better Living"; phonograph records entitled "Prescription for Better Living" and "Your Priceless Possession"; and booklets entitled "The Vi-San Story" and "Your Priceless Possession."

LIBELED: 4-18-58, E. Dist. Mich.

CHARGE: 502(a)—when shipped, the labeling accompanying the article contained false and misleading representations that the article was effective in preventing, treating, or alleviating digestive problems, loss of weight, fatigue, weakness, dry skin, hair, or nails, lusterless eyes, functional or organic diseases, arthritis, heart trouble, sinus trouble, chronic infections, virus infections, headaches, colds, constipation, emotional instability, lowered body efficiency, distorted heart rhythm, skin inflammations, mental confusion, dental caries, diarrhea, loss of manual dexterity, fear, complex, insomnia, neuritis, sores, poor blood coagulation, cancer, coronary thrombosis, allergies, cerebral palsy, multiple sclerosis, infantile paralysis, muscular dystrophy, epilepsy, nephrosis, tuberculosis, deafness, blindness, and diabetes; that the article was a necessary or required adjunct to diet since the average American had a serious dietary problem and consumption of proteins was far below optimum requirements;

that use of the article would be a major step toward better living; that it assured nutritional health; that it was never contraindicated; that it replaced elements absent from food grown on depleted soil; and that the great majority of people were benefited by the addition of even small quantities of essential vitamins and minerals to the daily diet.

**DISPOSITION:** Vi-San Co. filed a claim and entered into a stipulation with the Government pursuant to which the case was removed to the United States District Court for the Northern District of California on 6-16-58. Thereafter, on 11-14-58, the claimant withdrew its claim. On 12-23-58, a default decree of condemnation was entered, and the article was destroyed.

**5994. Arman's ear drops.** (F.D.C. No. 42385. S. No. 22-225 P.)

**QUANTITY:** 94 btls, at Council Bluffs, Iowa.

**SHIPPED:** 8-18-58 and 10-6-58, from Omaha, Nebr., by Arman Drug Co., Inc.

**LABEL IN PART:** "Contents 15 C.C. ARMAN'S EAR DROPS \* \* \* Manufactured by Arman Drug Co., Inc., Omaha, Nebraska Formula: Benzalkonium Chloride 1:1000, Chlorobutanol/Anhydrous/1 percent \* \* \* Benzocaine and Urea in a Propylene Glycol and Glycerin Base."

**LIBELED:** 11-28-58, S. Dist. Iowa.

**CHARGE:** 502(a)—when shipped, the label contained false and misleading representations that the article was an adequate and effective treatment for ear infections and earache.

**DISPOSITION:** 1-5-59. Consent—destruction.

**5995. Vibrating mattress.** (F.D.C. No. 41787. S. No. 1-801 P.)

**QUANTITY:** 11 devices at Roberta, Ga.

**SHIPPED:** 4-7-58, from St. Petersburg, Fla., by Pulsnation Enterprises, Inc.

**LABEL IN PART:** "Pulse-A-Rythm Massaging Mattress \* \* \* No. 2645 (or other number)."

**ACCOMPANYING LABELING:** Cards entitled "While You Sleep On A Pulse Rythm Mattress."

**RESULTS OF INVESTIGATION:** The device was essentially a spring filled mattress, one end of which enclosed a  $1\frac{1}{100}$  horse power electric motor attached to an off center shaft which provides a vibratory action.

**LIBELED:** 5-28-58, M. Dist. Ga.

**CHARGE:** 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for arthritis, bursitis, rheumatism, heart conditions, nervous tension, and painful muscles, and would increase circulation to bring fresh energy and nourishment to every part of the body.

**DISPOSITION:** 3-26-59. Default—the vibrator machinery was removed from the mattresses and destroyed. The mattresses were then delivered to charitable institutions.

**5996. Reduce-O-Matic pillow.** (F.D.C. No. 42501. S. No. 22-031 P.)

**QUANTITY:** 12 devices at Augusta, Kans.

**SHIPPED:** 5-9-58 and 6-5-58, from Wichita Falls, Tex., by Reduce-O-Matic Mfg. Co.

**LABEL IN PART:** (Metal plate on device) "Reduce-O-Matic \* \* \* Reduce-O-Matic Mfg. Co. \* \* \* Wichita Falls, Tex."



**ACCOMPANYING LABELING:** Leaflets entitled "1000 Calorie diet" and "Reduce-O-Matic," and card entitled "Reduce-O-Matic Guarantee."

**RESULTS OF INVESTIGATION:** The article was an upholstered, semi-rigid cushion-type device containing an electric motor capable of providing vibration.

**LIBELED:** 12-3-58, Dist. Kans.

**CHARGE:** 502(a)—when shipped, the labeling contained false and misleading representations that the article was an adequate and effective treatment for reducing weight, taking off "ugly fat"; breaking up lung congestion; strengthening back muscles and improving posture; relieving nervous tensions; increasing blood circulation to carry away excess fat; and breaking down fatty tissue.

**DISPOSITION:** 5-20-59. Consent—claimed by Robert M. Kiker, Augusta, Kans., and relabeled.

**5997. Relax-O-Matic mattress.** (F.D.C. No. 42972. S. No. 46-053 P.)

**QUANTITY:** 10 devices at Shreveport, La.

**SHIPPED:** 2-17-59, from San Antonio, Tex., by Relax-O-Matic Relaxing Equipment Co.

**LABEL IN PART:** "Your Invitation To Relaxation \* \* \* Relax-O-Matic Relaxing Equipment Massaging Mattress."

**ACCOMPANYING LABELING:** Folders entitled "Relax-O-Matic \* \* \* Your Invitation to Relaxation."

**LIBELED:** 4-9-59, W. Dist. La.

**CHARGE:** 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment as to man for relieving arthritis, bursitis, or rheumatism, for restoring energy, or for setting the mind and body on an even keel and unwind-ing taut nerves and muscles.

**DISPOSITION:** 6-8-59. Consent—claimed by Jefferson W. Hightower, Shreveport, La., and relabeled.

**5998. Relax-A-Tone massager.** (F.D.C. No. 42932. S. No. 3-126 P.)

**QUANTITY:** 19 devices in ctns. at Tampa, Fla., in possession of Thermal Massage, Inc.

**SHIPPED:** 11-24-58, from Los Angeles, Calif., by Relax-A-Cushion, Inc.

**LABEL IN PART:** (Ctn.) "Relax-A-Tone Human Hand Action Massage Unit Cycloid Massage."

**ACCOMPANYING LABELING:** Leaflets entitled "Topper Relax-A-Tone Hand Unit" and "Belle Femme," and card folders entitled "Life Can Be Wonderful."

**RESULTS OF INVESTIGATION:** The article was a small cylindrical-shaped device containing an electric motor capable of providing vibration, and intended as a hand unit to provide massage to the body.

The leaflet entitled "Belle Femme" and the card folders were prepared by the dealer, and the other leaflets were shipped with the devices.

**LIBELED:** 4-13-59, S. Dist. Fla.

**CHARGE:** 502(a)—when shipped and while held for sale, the labeling contained false and misleading representations that the article was an adequate and effective treatment for relieving rheumatism, bursitis, arthritis; stimulating and promoting circulation; breaking down fatty tissues; relieving

tension and muscular aches and pains; reducing weight without diet; removing "inches and pounds off your waist, hips and thighs"; increasing circulation to carry away waste fat; and providing deep massage to relieve tension and muscular pains.

DISPOSITION: 6-4-59. Default—destruction.

**5999. Electro-Warmth Bed Warmer.** (F.D.C. No. 42840. S. No. 40-250 P.)

QUANTITY: 5 individually cartoned devices at Moss Beach, Calif.

SHIPPED: 11-24-58, from Danville, Ohio, by Patented Products Corp.

LABEL IN PART: (Ctn.) "Electro-Warmth Automatic Bed Warmer Patented Products Corporation, Danville, Ohio"; (tag on device) "Electro-Warmth \* \* \* You Sleep On It Not Under It \* \* \* Patented Products Corp., Danville, Ohio."

ACCOMPANYING LABELING: Leaflets entitled "Sleeping Comfort and Health," "New Electro-Warmth," and "Electro-Warmth—It's Warm"; pamphlets entitled "Which Bed Warmer Works Best"; and printed sheets entitled "Here's Why Users Prefer Electro-Warmth."

RESULTS OF INVESTIGATION: The article consisted of a mattress pad containing a variable controlled heating element.

LIBELED: 2-20-59, N. Dist. Calif.

CHARGE: 502(a)—when shipped, the labeling accompanying the article contained false and misleading representations that the article was an adequate and effective treatment for relieving or curing arthritis, colds, chronic sinus and tonsil infections, organic pains, and neuritis; and that the article would provide better health and longer life.

DISPOSITION: 5-5-59. Default—destruction.

#### DRUG FOR VETERINARY USE

**6000. Paladide (veterinary).** (F.D.C. No. 42873. S. No. 51-481 P.)

QUANTITY: 26 25-lb. pails, 312 1-lb. jars, and 41 cases, each containing 12 1-lb. jars, at Chicago, Ill.

SHIPPED: Between 11-7-58 and 1-27-59, from Kansas City, Mo., by Jensen-Salsbery Laboratories, Inc.

LABEL IN PART: (Jar) "Jen-Sel \* \* \* therapeutic iodide compound PALADIDE \* \* \* Each ounce contains: Cuprous iodide\* . . . . 24.1 gr. Palatable, inert base \* \* \* Supplies 1.04 Gm. of available iodine."

ACCOMPANYING LABELING: Circular entitled "Jen-Sal Product Guide and Price List."

LIBELED: 3-6-59, N. Dist. Ill.; amended libel 3-31-59.

CHARGE: 502(a)—when shipped, the labeling contained false and misleading representations that the article was an adequate and effective treatment for lumpy jaw and respiratory diseases of cattle and swine, mastitis, metritis, and as supportive therapy in such conditions as functional sterility and cervical abscesses in cattle and swine.

DISPOSITION: 5-20-59. Default—destruction.

## INDEX TO NOTICES OF JUDGMENT D.D.N.J. NOS. 5981 TO 6000

## PRODUCTS

	N.J. No.		N.J. No.
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Alcoholism, remedy for-----	5981	Mattress, Relax-O-Matic-----	5997
Alcorem -----	5981	vibrating -----	5995
Anterior pituitary solution----	5986	Metrodyne tablets-----	5988
Arman's ear drops-----	5994	Mill Rue tonic-----	5991
Arthritis, remedies for. <i>See</i> Rheumatism, remedies, for.		Neuralgia, remedies for. <i>See</i> Rheumatism, remedies for.	
Bee Royale Capsules-----	<sup>1</sup> 5983	Neuritis, remedies for. <i>See</i> Rheumatism, remedies for.	
Bioplete tablets-----	5992	Nutri-Bio Food Supplement----	5987
Bladder conditions, remedy for--	5991	Paladide -----	6000
Bursitis, remedies for. <i>See</i> Rheumatism, remedies for.		Pangamic Acid capsules-----	5985
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Cardiobee 15 Injection-----	5985	Reduce-O-Matic pillow-----	5996
Cernelle Pollen tablets-----	5990	Rejuvenators -----	<sup>1</sup> 5983, 5990
Devices -----	5995-5999	Relax-A-Tone massager-----	5998
reducing -----	5996, 5998	Relax-O-Matic mattress-----	5997
vibrating-----	5995, 5996	Rheumatism, remedies for (de- vices) -----	5995, 5997-5999
Ear disorders, remedy for-----	5994	Royal jelly-----	<sup>1</sup> 5983
drops, Arman's-----	5994	Sciatica, remedies for. <i>See</i> Rheumatism, remedies for.	
Electro-Warmth Bed Warmer--	5999	Sinusitis, remedy for (device)--	5999
Giles veterinary medicine-----	5982	Tonic, Mill Rue-----	5991
Gout, remedies for. <i>See</i> Rheu- matism, remedies for.		Veterinary preparations-----	5982, 5985, 6000
HOC Hangover capsules-----	5989	Vibrating mattress-----	5995
Heart conditions, remedies for--	5995	Vi-San Food Supplement-----	5993
Ipecac root, fluid extract of----	5981	Vitamin preparations-----	5984, 5985, 5987, 5989
Ketovite tablets-----	5992		
Kidney conditions, remedy for---	5991		

## SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

	N.J. No.		N.J. No.
Arman Drug Co., Inc.:		HOC Laboratories, Inc.:	
Arman's ear drops-----	5994	HOC Hangover capsules-----	5989
Cernelle Pollen Co.:		Hallmark Laboratories, Inc.:	
Cernelle Pollen tablets-----	5990	vitamin B <sub>12</sub> injection-----	5984
Chase Chemical Co.:		Jensen-Salsbery Laboratories,	
Metrodyne tablets-----	5988	Inc.:	
Coastal Medical Supply Co.:		Paladide-----	6000
anterior pituitary solution----	5986	John Beard Memorial Founda- tion:	
Cook, G. R.:		Cardiobee 15 Injection and Pangamic Acid capsules----	5985
Nutri-Bio Food Supplement---	5987		
Giles Remedy Co.:			
Giles veterinary medicine-----	5982		

<sup>1</sup> (5983) Seizure contested. Contains opinions of the courts.



	N.J. No.		N.J. No.
Metro Products, Inc.:		Pulsnation Enterprises, Inc.:	
Metrodyne tablets-----	5988	vibrating mattress-----	5995
Midwest Health Aids:		Reduce-O-Matic Mfg. Co.:	
Alcorem-----	5981	Reduce-O-Matic pillow-----	5996
Nature Food Centres, Inc.:		Relax-A-Cushion, Inc.:	
Bee Royale Capsules-----	<sup>1</sup> 5983	Relax-A-Tone massager-----	5998
Nutri-Bio Products. <i>See</i> Cook,		Relax-O-Matic Relaxing Equip-	
G. R.:		ment Co.:	
Patented Products Corp.:		Relax-O-Matic mattress-----	5997
Electro-Warmth Bed Warmer-	5999	Thermal Massage, Inc.:	
Paxton, Roy:		Relax-A-Tone massager-----	5998
Mill Rue tonic-----	5991	Vi-San Co.:	
Professional Foods:		Vi-San Food Supplement-----	5993
Ketovite tablets and Bioplete		Vitamix Corp.:	
tablets-----	5992	anterior pituitary solution----	5986

<sup>1</sup> (5983) Seizure contested. Contains opinions of the courts.

# U.S. Department of Health, Education, and Welfare

## FOOD AND DRUG ADMINISTRATION

### NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

6001-6040

### DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were adulterated or misbranded within the meaning of the Act when introduced into and while in interstate commerce or while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings in which decrees of condemnation were entered by default, or by consent, and in one case following reversal by the appellate court of the judgment of the trial court; (2) criminal proceedings terminated upon a plea of guilty; and (3) an injunction proceeding terminated by dismissal after compliance. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation, and the criminal and injunction proceedings are against the *firms* or *individuals* charged to be responsible for violations.

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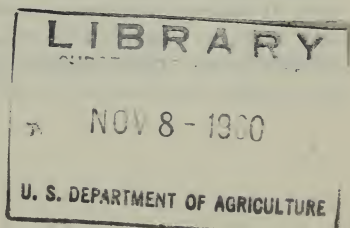
GEO. P. LARRICK, *Commissioner of Food and Drugs*.

WASHINGTON, D.C., October 11, 1960.

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\* For drugs actionable because of deviation from official or own standards, see No. 6003; omission of, or unsatisfactory, ingredient statements, No. 6012; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, No. 6025; labeling information not likely to be read and understood by the ordinary individual under customary conditions of purchase and use, No. 6005, 6012.



**SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS  
REPORTED IN D.D.N.J. 6001-6040**

*Adulteration*, Section 501(b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopoeia), and its quality and purity fell below the standard set forth in such compendium.

*Misbranding*, Section 502(a), the labeling of the article was false and misleading; Section 502(b) (1), the article was in package form and it failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; Section 502(c), a word, statement, or other information required by the Act to appear on the label or labeling was not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use; Section 502(e) (2), the article was a drug not designated solely by a name recognized in an official compendium, and it was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient and the proportion of alcohol contained therein; Section 502(f), the labeling of the article failed to bear (1) adequate directions for use; and (2) adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 502(j), the article was dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in its labeling; Section 503(b) (4), the article was subject to Section 503(b) (1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

*New-drug violation*, Section 505(a), the article was a new drug within the meaning of Section 201(p), which was introduced into interstate commerce, and an application filed pursuant to Section 505(b) was not effective with respect to such drug.

**DRUG ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED  
ACCORDING TO DIRECTIONS**

**6001. Quik-Kap Capsules and Rem-Al Emetic.** (F.D.C. No. 35122. S. Nos. 36-917 L, 38-356 L.)

**INFORMATION FILED:** 12-14-53, S. Dist. N.Y., against Leo Savitch, general manager of the Personal Drug Co., and the Rem-Al Drug Co., New York, N.Y.

**ALLEGED VIOLATION:** Between 9-27-51 and 10-16-51, while a number of capsules of drug were being held for sale at New York, N.Y., after shipment in interstate commerce, the defendant caused the capsules to be repacked into boxes labeled "*Quik-Kap Capsules*" and containing a leaflet entitled "Instruction Leaflet and Order Blank" which act of repacking resulted in such drug in the boxes being misbranded.

In addition, on 9-20-51, the defendant caused to be introduced into interstate commerce, at New York, N.Y., for delivery to Birmingham, Ala., a bottle of *Rem-Al Emetic* which was misbranded.

**LABEL IN PART:** "QUIK-KAP Capsules For \* \* \* PERSONAL DRUG CO. 6  
HESTER ST. NEW YORK 2, N.Y. AVERAGE DOSE \* \* \* ACTIVE



**INGREDIENTS:** Black Cohosh (Powd. Ext. Cimicifuga) 0.0065 Gm. Wind Flower (Powd. Ext. Pulsatilla) 0.0065 Gm. Ferrous Sulfate U.S.P. Manganese Dioxide Thiamine Hydrochloride U.S.P. (Vit. B<sub>1</sub>) 0.001 Gm."; and (front panel) "½ OUNCE Rem-Al Emetic Brand of Fluid Extract of Ipecac-Alcohol 30% Distributed by REM-AL DRUG CO. 2 SUFFOLK STREET NEW YORK 2, N.Y."; (back panel) "DIRECTIONS Put 15 to 20 drops of REM-AL in a large drink of alcoholic beverage. Half hour later give a small drink using 15 to 20 drops of Rem-Al. NOTE: Use only as directed above and by directions accompanying bottle. CAUTION: Do not use in heart, liver, kidney, circulatory diseases, pregnancy, stomach ulcers, high blood pressure or serious disorder without consulting your physician."

**CHARGE:** 502(a)—the labeling of the articles contained false and misleading representations that the *Quik-Kap capsules* were an adequate and effective treatment for delayed or irregular menstruation, and that the *Rem-Al Emetic* was an adequate and effective treatment for drunkenness; and 502(j)—the *Rem-Al Emetic* was dangerous to health when used in the dosage prescribed, recommended, and suggested in its labeling.

**PLEA:** Guilty.

**DISPOSITION:** 1-15-60. \$1,000 fine, suspended sentence of 90 days in jail, and probation for 1 year.

#### NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

**6002. Grisovin tablets (2 seizure actions).** (F.D.C. Nos. 43172, 43194. S. Nos. 56-794 P, 56-803 P.)

**QUANTITY:** 3 1,000-tablet btls. at Miami, Fla.

**SHIPPED:** Between 4-27-59 and 5-4-59, from New York, N.Y., by Overseas Pharmaceutical Co.

**LABEL IN PART:** "Grisovin 250 Mg. Griseofulvin Glaxo Laboratories, Greenford, England."

**LIBELED:** 6-19-59 and about 6-25-59, S. Dist. Fla.

**CHARGE:** 505(a)—the article was a new drug which may not be introduced or delivered for introduction into interstate commerce, since an application filed pursuant to law was not effective with respect to such drug.

**DISPOSITION:** 8-17-59. Default—destruction.

**6003. Vitamin B<sub>12</sub> injection.** (F.D.C. No. 40930. S. No. 67-040 M.)

**QUANTITY:** 144 10-cc. vials at Baltimore, Md.

**SHIPPED:** 9-18-57, from Chicago, Ill., by Maizel Laboratories, Inc.

**LABEL IN PART:** "Intramuscular 10 cc Intravenous VITAMIN B<sub>12</sub> INJECTION Cyanocobalamin U.S.P. 1000 mcg. Each cc. contains a sterile solution of 1000 micrograms Vitamin B<sub>12</sub> U.S.P. (Cyanocobalamin) in normal saline with 2% Benzyl Alcohol as preservative. \* \* \* 28590."

**RESULTS OF INVESTIGATION:** Examination showed that each cubic centimeter of the article contained 1,039 micrograms of cyanocobalamin (vitamin B<sub>12</sub>), 9.88 milligrams of sodium chloride, and a quantity of unidentified dissolved material.

**LIBELED:** 11-1-57, Dist. Md.

**CHARGE:** 501(b)—when shipped, the quality and purity of the article fell below the standard for *cyanocobalamin injection* set forth in the United States

Pharmacopoeia since it contained a substantial amount of unidentified dissolved material which is not permitted by the standard as an ingredient of *cyanocobalamin injection*; and 505(a)—the article, because of the presence of unidentified dissolved material, was a new drug within the meaning of the law and an application filed pursuant to the law was not effective with respect to such drug.

**DISPOSITION:** Maizel Laboratories, Inc., claimant, filed an answer denying that the article was adulterated or a new drug as charged. The Government filed written interrogatories to which claimant objected in part. After a hearing, the claimant was required to answer all of the interrogatories but eight. Subsequently, the Government filed additional interrogatories which claimant answered. Thereafter, claimant having consented, on 8-10-59, a decree of condemnation was entered and the article was destroyed.

**6004. Enerjol capsules.** (F.D.C. No. 41276. S. Nos. 85-201/4 M.)

**QUANTITY:** 5,213 btls. of double strength capsules, and 2,733 btls. of single strength capsules, at Chicago, Ill., in possession of Owen Laboratories.

**SHIPPED:** 11-18-57 and 12-5-57, from Long Island City, N.Y.

**LABEL IN PART:** "60 (or other number) Capsules Lot No. 30019 ENERJOL DOUBLE STRENGTH Each Capsule contains: Thiamin Chloride 20 mgm. Riboflavin 10 mgm. Vitamin E (as D-alpha tocopherol acid succinate) 10 I. U. Vitamin B-12 Cobalamin conc. 10 mcgm. Iron (from ferrous gluconate) 20 mgm. Oyster Shell Powder 25 mgm. Royal Jelly 25 mgm. Iodine (from potassium iodide) 0.2 mgm. For use as a Dietary Supplement: One capsule daily." or "SINGLE STRENGTH Each capsule contains: Thiamin chloride 10 mgm. Riboflavin 5 mgm. Vitamin E (as D-alpha tocopherol acid succinate) 5 I. U. Vitamin B-12 Cobalamin conc. 5 mcgm. Iron (from ferrous gluconate) 10 mgm. Oyster Shell Powder 20 mgm. Royal Jelly 12.5 mgm. Iodine (from potassium iodide) 0.1 mgm. For use as a dietary supplement."

**ACCOMPANYING LABELING:** Circulars entitled "Owen Laboratories. The Enerjol Plan With Royal Jelly The Queen Bees Answer to Long Life" and "Discovered: New Wonder Capsule so Potent It Actually 'Combats Ills of Old Age' \* \* \* Helps Put back Power Into Important Bodily Functions."

**LIBELED:** 12-9-57, N. Dist. Ill.; libel amended 12-19-57.

**CHARGE:** 502(a)—while held for sale, the labeling which accompanied the article contained false and misleading representations that the article was an adequate and effective treatment for glandular diseases, tiredness, sexual deficiency, nervous tension, dizziness, lack of sleep, loss of mental and physical ambition, lack of appetite, increasing longevity, and weakened, tired eyes; and 505(a)—the article was a new drug within the meaning of the law and an application filed pursuant to the law was not effective with respect to such drug.

**DISPOSITION:** Owen Laboratories appeared as claimant and filed an answer denying that the drug was misbranded or a new drug. Thereafter, the Government filed written interrogatories against the claimant. On 4-30-58, the claimant requested additional time to answer the interrogatories, which was granted. Thereafter, on 5-8-58, the claimant filed objections to the interrogatories. Subsequently the Government filed a motion to have the objections stricken since additional time had not been granted for claimant to object to the interrogatories. The court thereupon, on 5-21-58, ordered that the



objections to the interrogatories be stricken. The court further ordered, on 5-26-58, that the interrogatories be answered.

On 6-4-58, the claimant then filed a motion to dismiss and for summary judgment. The court, on 9-8-58, entered the following memorandum opinion denying the claimant's motion to dismiss and for summary judgment:

SULLIVAN, *District Judge*: "This is a libel of information brought by the Government under Title 21 U.S.C. § 334, for the condemnation of certain bottles of a drug called 'Enerjol.' The condemnation is sought on the grounds that the contents of the bottles are misbranded under Sec. 352(a), and that 'Enerjol' is a 'new drug' under Section 355(a), as to which no effective application has been filed under Section 355(b).

"The claimant has moved to dismiss the libel and for a summary judgment. The sole basis for the motion is that in September, 1957, claimant entered into an agreement with the Post Office Department in an action brought against claimant by that Department under the provisions of Title 39 U.S.C. Sections 259 and 732, and allegedly concerned with the same product and same labels as those here involved. It is claimant's position that in view of the contents of the bottles are misbranded under Sec. 352(a), and that the agreement in the post office action is a bar 'in effect akin to the legal principles of *res adjudicata*.'

"The last argument is clearly in error. The doctrine of *res adjudicata* applies only when there has been an actual adjudication of the same issues in a prior proceeding. (*United States v. International Building Co.*, 345 U.S. 502, 505(1953)). Such is not the case here. In the Post Office proceeding, the issue was actual intent to deceive by means of false or of fraudulent pretenses (*Reilly v. Pinkus*, 338 U.S. 276(1949)). Here, the issue is whether the article is misbranded. It is settled in this Circuit that 'the offense of using the mails to defraud and the offense of introducing or delivering for introduction into interstate commerce misbranded drugs are not the same, and hence there is no *res judicata*.' (*United States v. Kaadt*, 171 F. 2d 600, at 605 (7th Cir. 1949); see also *United States v. 42 Jars*, etc. 160 F. Supp. 818, 821 (D.N.J. 1958).

"Claimant argues that he is not contending that the traditional doctrine of *res adjudicata* applies, but that something 'akin' to it is involved. This argument also must fail. However far one might stretch the traditional doctrine, it must at least involve some form of prior adjudication definite enough to form a standard against which the current action can be measured. In the instant situation there was no adjudication of any sort in the Post Office action. The agreement (attached to the motion) shows that claimant there merely agreed to refrain from making certain representations in the future. If this amounts to anything, it is an admission by claimant against his interests in this suit. Finally, the agreement provides that it 'will not act as a defense for violation of any other statute.' This in itself should preclude its use here.

"The argument that claimant is being subjected to 'multiplicity of actions' and 'undue harassment' is a specious one. It is perfectly apparent that the purposes and effect of the Post Office action and one for condemnation are entirely different and that the two remedies are properly distinct and co-existent. (*United States v. One Dozen Bottles*, 146 F. 2d 361, 363 (4th Cir., 1944)).

"For the foregoing reasons, the motions to dismiss and for a summary judgment are denied."

On 10-8-58, the Government filed a motion for entry of default decree since the claimant had failed to answer the interrogatories as ordered by the court. A default decree of condemnation was entered on 10-22-58. The claimant then filed notice of appeal to the United States Court of Appeals for the Seventh Circuit. On 3-31-59, the court of appeals handed down the following opinion affirming the judgment of the district court (265 F. 2d 332):



HASTINGS, *Circuit Judge*. "The Government, libelant-appellee, brought this action under the provisions of the Federal Food, Drug and Cosmetics Act, 21 U.S.C.A. §§ 301 et seq., for the condemnation and seizure of a drug called 'Enerjol.' The corporate claimant, Owen Laboratories, Inc., refused to answer the libelant's interrogatories on the ground of self-incrimination and the district court thereupon entered a default decree of condemnation. This appeal is taken from that decree and from an order of the district court denying claimant's motion for dismissal of the libel and for summary judgment.

"The instant suit was commenced in December of 1957. The amended libel charged that the drug, 'Enerjol,' was misbranded while held for sale after shipment in interstate commerce within the meaning of 21 U.S.C.A. § 352(a), and also alleged that the drug was a 'new drug' which was introduced into interstate commerce without an effective new drug application as provided in 21 U.S.C.A. § 355 (a) and (b).

"Prior to this action, in September of 1957, the Post Office Department had issued a fraud complaint against Owen Laboratories, Inc., charging it with having obtained money through the mails by means of fraudulent representations regarding the nature of and benefits to be obtained from the so-called 'Enerjol Capsules.' In order to avoid having a fraud order entered against it, Owen Laboratories filed an 'Affidavit of Agreement' in which it consented to cease making the representations charged to be fraudulent in the Post Office complaint.

"Claimant moved for a dismissal of the instant suit and for summary judgment, on the ground that the agreement with the Post Office, entered into after initiation of the mail fraud proceeding, was, in effect, an adjudication<sup>1</sup> with respect to the identical product, the identical literature and identical issues involved in this libel; and that the agreement 'constitutes a bar to the present action and is in effect akin to the legal principle of *res adjudicata*.' The district court denied this motion setting forth its reasoning in a brief memorandum opinion which indicates that it fully understood and rejected claimant's arguments made before that court and renewed in this appeal. We hold that the district court committed no error in denying this motion.

"The mail fraud proceeding could not possibly be a bar to the instant action. In the first place, the agreement executed by claimant in connection with the mail fraud proceeding is, by its own express terms and contrary to claimant's contentions, not an approval or ratification of any business conducted or to be conducted by claimant. The agreement further states expressly that 'its filing will not act as a defense or relieve the undersigned [claimant's president] of responsibility for violation of any other statute \* \* \*.'

"Further, when stripped of its refinements, claimant's position appears to be that the Postmaster General, with his limited authority under the mail fraud statutes, could and should have somehow effectively enforced the provisions of the Federal Food, Drug and Cosmetics Act; and that, since he did take some action, as evidenced by the agreement, the Government is now barred from enforcing that Act against the offending product.

"Viewing claimant's contentions in this light merely points up the fact that the proceeding under the mail fraud statute and the instant one differ not only as to issues involved, but also as to purpose and effect. The Postmaster General has only the limited authority to prohibit the fraudulent use of the mails, and the sole purpose of a mail fraud proceeding is to enjoin the continuation of conduct found fraudulent. *Donaldson v. Read Magazine, Inc.*, 333 U.S. 178, 191 (1948). There must be proof of a fraudulent purpose, an actual intent to deceive, on the part of the alleged violator. *Reilly v. Pinkus*, 338 U.S. 269, 276 (1949).

"On the other hand, the present suit under the Food, Drug and Cosmetics Act has as its purpose the seizure and actual removal of the allegedly offending articles from the channels of trade. Under this Act, no proof of wrongful or fraudulent intent is required either in criminal proceedings brought under its provision, *United States v. Dotterweich*, 320 U.S. 277, 281, 284-285 (1943), or in seizure cases such as the instant one. *Research Laboratories v. United*

<sup>1</sup> By "adjudication" claimant refers to any type of administrative action. It argues extensively in its brief for the adoption by this court of a new rule of "res administrata" embodying principles "akin to the legal principle of *res adjudicata*" but tailored to fit problems peculiar to administrative law.

*States*, 9 Cir., 167 F. 2d 410, 420-421 (1948) ; *United States v. Five Cases, etc.*, 2 Cir., 156 F. 2d 493, 495 (1946). The Supreme Court in *Dotterweich* pointed out that by this Act, as amended in 1938:

\* \* \* Congress extended the range of its control over illicit and noxious articles \* \* \*. The purposes of this legislation thus touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self protection. \* \* \* In the interest of the larger good it puts the burden of acting at hazard upon a person otherwise innocent but standing in responsible relation to a public danger." *United States v. Dotterweich*, *supra* at 280-281.

In the libel in this case the drug is alleged to be subject to seizure not only as misbranded (falsely labeled) but also as a new drug introduced into interstate commerce without an effective new drug application to establish its safety as is required by law. The proceeding and resulting agreement under the mail fraud act could be no bar to this suit.

"Reliance by claimant on *United States v. Willard Tablet Co.*, 7 Cir., 141 F. 2d 141 (1944) is misplaced. In that case, a prior decision by the Federal Trade Commission had *approved* statements used by an alleged violator and ruled that the statements were not false representations. We held that a subsequent condemnation proceeding, under the Federal Food, Drug and Cosmetics Act based on identical statements as to the same product was barred, on principles of *res adjudicata*, because the same issues and elements of proof were involved in both proceedings. The case of *George H. Lee Co. v. Federal Trade Commission*, 8 Cir., 113 F. 2d 583 (1940) also cited by claimant is to the same effect.

"Claimant also relied heavily, in its brief, on the case of *United States v. Radio Corporation of America and National Broadcasting Company, Inc.*, E.D. Pa., 158 F. Supp. 333 (1958). In that case the district court decided that approval by the Federal Communications Commission of a proposed exchange of radio and television stations, precluded a subsequent suit in which the Government sought to upset the transaction as violative of the anti-trust laws. However, just prior to oral argument in the present case, the Supreme Court of the United States, having noted probable jurisdiction at 357 U.S. 918 (1958), unanimously reversed the district court. *United States v. Radio Corporation of America and National Broadcasting Company, Inc.*, . . . U.S. . . . (1959).<sup>2</sup> The Supreme Court held that the Federal Communications Commission had no power to decide anti-trust issues as such and that, consequently, its determination that the 'public interest, convenience and necessity' would be served by the proposed exchange of radio and television stations did not bar the subsequent anti-trust suit. In so doing the Court found *res judicata* principles inapplicable since, as in the instant case, different issues were involved. *Id.* at . . . In our view, this holding alone would be completely dispositive of claimant's contention.

"It is next contended that the district court erred in entering the default decree of condemnation upon claimant's failure to answer libellant's interrogatories. The refusal of the corporation to answer was based on an assertion of a claim of privilege against self-incrimination. However, it is settled beyond possible doubt that a corporation has no such privilege to assert. *United States v. White*, 322 U.S. 694 (1944). In the *White* case, the Supreme Court stated clearly and unequivocally:

The constitutional privilege against self-incrimination is essentially a personal one applying only to natural individuals.

\* \* \* [I]t cannot be utilized by or on behalf of any organization, such as a corporation. (Emphasis added.) (*id.* at 698-699).

See also *Fleming v. Montgomery Ward*, 7 Cir., 114 F. 2d 384, 386-387 (1940), cert. den., 311 U.S. 690.

"In the face of this, claimant urges that a corporation may somehow assert the privilege against self-incrimination on behalf of itself, and a broad class of corporate officers and agents, because of what it terms the unique

<sup>2</sup> Mr. Justice Frankfurter and Mr. Justice Douglas took no part in the consideration or decision of the case.



nature of the Federal Food, Drug and Cosmetics Act which imposes criminal liability on officers and agents of the corporation without requiring proof of wrongful intent or consciousness of wrongdoing.

"It is true that this Act is an example of the so-called 'public welfare statute' which requires no proof of wrongful intent. *Morissette v. United States*, 342 U.S. 246, 255-256 (1952); *United States v. Dotterweich*, 320 U.S. 277 (1943). However, criminal liability is not, as claimant seems to contend, imposed automatically under this type of law upon every officer or agent no matter how remote his connection with the offending corporation. In *Dotterweich*, the Supreme Court clearly enunciated the proper test. Criminal responsibility for violation of the Federal Food, Drug and Cosmetics Act attaches to those who have a responsible share in the furtherance of the transaction which the statute outlaws. 'Whether an accused shares responsibility in the business process resulting in unlawful distribution depends on the evidence produced at the trial and its submission—assuming the evidence warrants it—to the jury under proper guidance.' (Emphasis added.) *U.S. v. Dotterweich*, *supra* at 284.

"It was the duty of this corporate claimant to select an agent who, without fear of self-incrimination, could provide the information requested. The interrogatories were addressed to the corporation and the answer sought was that of the corporation. There is no merit in claimant's suggestion that the answers to the interrogatories must be verified by an officer or managing agent of the corporation. Rule 33 of the Federal Rules of Civil Procedure, 28 U.S.C.A., provides that 'any officer or agent' of a corporate party 'shall furnish such information as is available to the party.' It would indeed be incongruous to permit a corporation to select an individual to verify the corporation's answers, who because he fears self-incrimination may thus secure for the corporation the benefits of a privilege it does not have.

"The default decree was entered by the district court pursuant to Rule 37(d) F.R.C.P., 28 U.S.C.A., which provides:

If a party or an officer or managing agent of a party wilfully fails to appear before the officer who is to take his deposition, after being served with proper notice, or fails to serve answers to interrogatories submitted under Rule 33, after proper service of such interrogatories, the court on motion and notice may \* \* \* enter a judgment by default against the party.

Claimant asserts that there was no wilful failure to answer since the officer of the corporation, in this case the president, properly asserted his constitutional privilege against self-incrimination even if the corporation had no such privilege. We have answered this contention above. Claimant had a duty to appoint an agent who could, without fear of self-incrimination, furnish such requested information as was available to the corporation. No attempt was made to do so.

"The disjunctive wording of the rule, above, would seem to indicate that a showing of wilfulness is necessary only on failure to appear for deposition. Assuming that such is not the case, however, we hold that what is intended by 'wilful failure' to comply with the rule is any intentional failure as distinguished from involuntary noncompliance. No wrongful intent need be shown. *Brookdale Mill Inc. v. Rowley*, 6 Cir., 218 F.2d 728, 729 (1954).

"But beyond that, we are singularly unimpressed with claimant's arguments, in view of the following statement made by claimant's president in an affidavit accompanying the motion to dismiss and for summary judgment: 'I have not made any false or improper claims in connection with the marketing of this product. My products are marketed based upon extensive research and consultation with experts.' Thus, though first representing to the court that it had such information available and implicitly offering it in support of this motion, when it was later served with interrogatories seeking details of such 'extensive research and consultation,' claimant asserted its claimed privilege.

"Finally, *Societe Internationale v. Rogers*, 357 U.S. 197 (1958) relied on by claimant is inapposite since in that case the Supreme Court felt that dismissal under Rule 37 was too harsh a remedy where there was evidence of a good faith effort to comply with the rule. No attempt was made to comply in this case.



"We hold that the trial court did not err in entering the default decree upon proper motion by the Government and notice to claimant.<sup>3</sup>

"The judgment and decree of condemnation is AFFIRMED."

Thereafter, the claimant filed a petition for writ of certiorari with the United States Supreme Court, which petition was denied on 6-29-59 (360 U.S. 931). The article and the accompanying circulars were subsequently destroyed in accordance with the terms of the decree of condemnation.

## DRUG IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

6005. Tranquil. (F.D.C. No. 39871. S. Nos. 60-309 M, 60-361 M.)

QUANTITY: 317 btls. at Detroit, Mich.

SHIPPED: 12-26-56 and 1-25-57, from Chicago, Ill., by State Pharmacal Co.

LABEL IN PART: "Tranquil \* \* \* Alva Laboratories \* \* \* Active Ingredients:

Each Tranquil contains in grams: Scopolamine Aminoxide Hydrobromide .00010; Methapyraline Hydrochloride N. N-Dimethyl-N' (2 Thenyl)-N' (2-Pyridyl)-Ethylenediamine Hydrochloride; Bromides; Sodium .09700, Potassium .19400, Ammonium .03285; Niacin; Niacinamide; Thiamine Hydrochloride; Riboflavin; Cyanocobalamin; Stomach and Liver whole desiccated (containing entire B Complex); Ferric Pyrophosphate, Acetanilid .05000; \* \* \* Tranquil is Multiaction and embodies recent scientific developments in reducing nervous tension."

ACCOMPANYING LABELING: Leaflet in each bottle entitled "TRANQUIL—An aid in relief of nervous tension"; leaflets for druggists entitled "MR. DRUGGIST"; and display cartons reading in part: "Safe TRANQUILIZING AID."

LIBELED: 2-15-57, E. Dist. Mich.; amended libel 6-8-59.

CHARGE: 502(a)—when shipped, the name of the article "Tranquil" and the labeling of the article contained false and misleading representations that the article was one of the recently developed "tranquilizing" drugs and that it would produce all of the effects capable of being produced by a true "tranquilizer" drug; 502(c)—the ingredient statements required by 502(e) (2), and the warnings required by 502(f) (2), to appear in the labeling of the article were not prominently placed thereon with such conspicuousness and in such terms, as to render the required ingredient statements and warnings likely to be read and understood by the ordinary individual under customary conditions of purchase and use; 502(f) (2)—the labeling of the article failed to warn that frequent or continued use of the article may cause serious blood disturbances and mental derangement, and that the article should not be taken by persons suffering from glaucoma or increased intraocular pressure unless upon the advice of a physician; and 503(b) (4)—the article was a drug sub-

<sup>3</sup>In their briefs both parties refer to *United States v. 42 Jars, etc.*, \* \* \* *Bee Royale Capsules*, D.C.D. N.J., 160 F. Supp. 818 (1958) and 162 F. Supp. 944 (1958), and note an appeal pending therefrom in the Third Circuit. In an opinion filed March 12, 1959, the Court of Appeals for the Third Circuit affirmed, deciding the issues identical to those considered in the instant appeal agreeable with the result reached in this opinion, *viz*: that the action taken by the Post Office Department upon its fraud complaint and subsequent settlement was no bar to the action brought under the Federal Food, Drug and Cosmetics Act, (thus rejecting the proposed rule of "*res administrata*," see note 1, *supra*); that the corporate claimants could not resort to the Fifth Amendment as a basis for refusing to answer interrogatories, and that it was within the trial court's discretion to enter a default judgment under Rule 37(d), F.R.C.P., 28 U.S.C.A., by reason of such failure to answer. Thus, we find ourselves in complete agreement with the Third Circuit although, in our consideration and determination of this case we did not have the benefit of its prior holding.

ject to a 503(b) (1) (B), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: Alva Laboratories, Inc., Chicago, Ill., the manufacturers of the article, appeared as claimant and filed an answer to the libel denying that the article was misbranded as alleged. Interrogatories were thereafter served upon the claimant by the Government. The claimant subsequently filed objections to answering the interrogatories. The matter came on for hearing before the court on 10-15-57, with the result that the court ordered the claimant to answer certain interrogatories and arranged for a further hearing on the matter of answering the remaining interrogatories. The claimant filed answers to some of the interrogatories on 11-14-57. Thereafter, the case remained pending to permit claimant to consider the matter of revising the labeling of the article.

On 5-4-59, the Government filed a motion to amend the libel to include the charge of 503(b) (4), as stated above, and a motion to compel further answers to the Government's interrogatories. The motion to amend the libel was granted on 6-8-59, and the motion to compel further answers to the interrogatories was granted on 8-10-59.

Thereafter, a stipulation signed by the attorneys for the claimant, the claimant's president, and the Government's attorneys was filed consenting to the entry of a decree of condemnation and acknowledging that the article was misbranded when introduced into interstate commerce in that the labeling of the article failed to bear adequate warnings for use in certain pathological conditions, namely, that the article should not be taken by persons suffering from glaucoma or increased intraocular pressure unless upon advice of a physician. Pursuant to such stipulation, the court, on 12-7-59, ordered that the article be condemned and destroyed.

## DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS\*

### 6006. Various drugs. (Inj. No. 326.)

COMPLAINT FOR INJUNCTION FILED: 3-31-58, E. Dist. Wis., against Adolph Fictum, t/a Wm. Horner Co., and Wm. M. Horner Co., Green Bay, Wis., to enjoin and restrain the defendant from doing acts resulting in the misbranding of various bulk drugs and repackaged drugs, while held for sale after shipment in interstate commerce, and from introducing and delivering for introduction into interstate commerce, various bulk or repackaged drugs which were misbranded.

NATURE OF BUSINESS: The defendant was engaged in manufacturing, packing, mixing, selling, and distributing, singly and in combination the following drugs:

*Wm. M. Horner's Pure Herb Health Tea* or *Horner's Herb Tea* which contained senna leaves, uva ursi flowers, cascara sagrada, Spanish aniseed, licorice root, fennel seed, elder flowers, and dandelion root.

*Wm. M. Horner's Ointment for Eczema and Skin Diseases* which contained petrolatum, sulfur, oil of tar, creosol, phenol, and olive oil.

*Wm. M. Horner's Pure Herb Laxative* which contained cascara, cinnamon, cloves, nutmeg, and glycerine.

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\*See also No. 6005.

*Wm. M. Horner's Liniment for Rheumatism and Lumbago* which contained tincture of iodine and phenol.

*Wm. M. Horner's Laxative for Gall Stone Treatment* which contained Epsom salts and Rochelle salts.

*Wm. M. Horner's Gall Stone Remedy for Inflammation of the Gall Bladder or Duct* which contained olive oil, glycerine, and rhubarb.

*Wm. M. Horner's Kidney Remedy* which contained rhubarb, glycerine, and magnesia.

*Horner's Uterine Douche Powder* which contained sodium bicarbonate, alum, and sulfur.

*Wm. M. Horner's Nerve Tonic for Men and Boys* which contained catnip, boneset, camomile, hops, veronica, quassia chips, squill, caraway seed, cinnamon bark, glycerine, mandrake, elderberry bark and dandelion root.

*Horner's Menthol Ointment* which contained petrolatum, camphor, menthol crystals, liquid menthol, spirits of camphor, and peppermint.

*Horner's Inhalant* which contained spirits of camphor, menthol, ammonia and spirits of peppermint.

*Wm. M. Horner's Dyspepsia Powder for Indigestion and Gas on Stomach* which contained sodium bicarbonate, sodium chloride, cream of tartar, and pepsin.

*Wm. M. Horner's High Blood Pressure or Hardening of the Arteries* which contained catnip, yarrow flour, sassafras root, yellow dock root, quassia chips, garlic, camomile and peppermint.

*Wm. M. Horner's Body Builder* which contained gentian root, yellow dock root, sassafras root, camomile, juniper, dandelion root, wine, tincture of iodine, cascara and glycerine.

*Wm. M. Horner's Blood and Stomach Tonic* which contained petrolatum, cascara, cinnamon, cloves, and nutmeg.

*Wm. M. Horner's Nerve Remedy for Female Disorders* which contained catnip, boneset, camomile, hops, veronica, quassia chips, squill, caraway seed, cinnamon bark and glycerine.

The above-mentioned ingredients of the drugs were received in bulk from interstate sources.

**ALLEGED VIOLATION:** The defendant was causing labeling to accompany the above-named drugs, and the bulk drugs intended for use as ingredients thereof, which act was done while the drugs were held for sale by the defendant after shipment in interstate commerce and resulted in the drugs being misbranded as hereinafter described.

The defendant was also causing *Horner's Pure Herb Health Tea* or *Horner's Herb Tea* and *Wm. M. Horner's Ointment for Eczema and Skin Diseases* to be introduced and delivered for introduction into interstate commerce in a misbranded condition as hereinafter described.

**CHARGE:** The complaint alleged that the drugs were misbranded as follows:

(a) that the *Wm. M. Horner's Pure Herb Health Tea* or *Horner's Herb Tea* were misbranded when shipped in interstate commerce and, that while held for sale by the defendant, such drugs together with the bulk drugs for use as ingredients thereof were misbranded in the following respects:

502(a)—the labeling of the drugs contained false and misleading representations that the articles were adequate and effective in the treatment of constipation, bowel trouble, stomach, kidney, and bladder trouble, pimples, gas, indigestion, and tired feeling; the labeling falsely designated



the articles as a "Tea"; the labeling statements "Nature has given us Roots and Herbs for many ailments yet how sadly does the present generation neglect them" and "Why Not Use Herbs and Roots when nature has produced them for many ills of mankind" were false and misleading since such statements represented and suggested that the articles were adequate and effective in the treatment of all the ailments of mankind, whereas, the article was not adequate and effective in the treatment of all the ailments of mankind; and

502(f)—the labeling of the articles (1) failed to bear adequate directions for use for the purposes for which they were intended; and (2) such adequate warnings against use in those pathological conditions, or by children, where their use may be dangerous to health, or against unsafe dosage and duration of administration, in such manner and form, as are necessary for the protection of users since the articles were essentially laxatives, and their labeling failed to warn that the article should not be taken when abdominal pain (stomach ache, cramps, colic), nausea, vomiting (stomach sickness), or other symptoms of appendicitis were present; and their labeling also failed to warn against frequent or continued use since such use may result in dependence on laxatives to move the bowels;

(b) that the Ointment for Eczema and Skin Diseases was misbranded when shipped in interstate commerce, and, that while held for sale by the defendant, such drug together with the bulk drugs for use as ingredients thereof were misbranded in the following respect:

502(a)—in that their labeling was false and misleading since the articles were not effective in the treatment of eczema and all skin diseases;

(c) that the Pure Herb Laxative, Liniment for Rheumatism and Lumbago, and Laxative for Gall Stone Treatment and the bulk drugs used as ingredients thereof were, while held for sale by the defendant, misbranded in the following respects:

502(a)—the labeling of the articles contained false and misleading representations that the Pure Herb Laxative was an adequate and effective treatment for chronic constipation, biliousness, headaches, bad breath, and excessive gas in the stomach; that the Liniment for Rheumatism and Lumbago was an adequate and effective treatment for rheumatism, lumbago, and external inflammation, swelling and pain; and that the Laxative for Gall Stone Treatment was an adequate and effective treatment for gall stones;

502(f)(1)—the labeling of all three articles failed to bear adequate directions for use for the purposes for which they were intended;

502(f)(2)—the labeling of the articles failed to bear warnings against unsafe dosage and duration of administration and application since the articles "Herb Laxative" and "Laxative for Gall Stone Treatment" were essentially laxatives and their labeling failed to warn that the articles should not be taken when symptoms of appendicitis are present and that frequent or continued use of the articles may result in dependence on laxatives; and since the article "Liniment for Rheumatism and Lumbago" was a counter-irritant containing phenol (carbolic acid) and its labeling failed to warn that use of the article may cause excessive irritation, that the user should avoid getting it into the eyes or on mucous membranes, that when applied to the fingers and toes a bandage should not

be used, and that the article should not be applied to large areas of the body;

(d) that the remainder of the above-named drugs and the bulk drugs used as ingredients thereof were misbranded, while held for sale by the defendant, in the following respects :

502(a)—the labeling of the articles contained false and misleading representations that the Gall Stone Remedy for Inflammation of the Gall Bladder or Duct was an adequate and effective treatment for gallstones and gallstone colic; that the Kidney Remedy was an adequate and effective treatment for kidney stones, bed wetting, and weakened kidneys; that the Uterine Douche Powder was an adequate and effective treatment for irrigation of the vaginal tract and as a uterine douche; that the Nerve Tonic for Men and Boys was an adequate and effective treatment for hysterics, nervous irritability, inducing natural sleep, calming the nerves in general, malfunction of the digestive tract or kidneys, mental strain, sickness, impaired nutrition, nervousness, tired and worn-out feeling, loss of ambition, facial pallor, tiring easily at work, headaches, dizziness, sleeplessness, and traveling aches in various parts of the body; that the Menthol Ointment was an adequate and effective treatment for muscular rheumatism, nasal catarrh, head cold, sinus, cuts, bruises, chapped hands and insect bites; that the Inhalant was an adequate and effective treatment for sinus, catarrh, asthma and hay fever; that the Dyspepsia Powder for Indigestion and Gas on Stomach was recommended as an adequate and effective treatment for indigestion, gas on stomach, gastritis, to supplement and restore the gastric juice, sick headache, dizziness, sour stomach, heartburn, nausea, nervousness, bloating of the stomach and bowels, dyspepsia, inability to eat certain foods, and constipation; that the article for High Blood Pressure or Hardening of the Arteries was an adequate and effective treatment for high blood pressure, hardening of the arteries, over-eating, over-work, worry, headaches, dizziness, pain around the heart, obscure nervous disorders, angina pectoris and breaking-down of the functioning of the kidneys; that the Body Builder was an adequate and effective treatment for weak and run-down conditions of men and women, to excite secretions, to relax constrictions, to soothe nerves, no appetite, for the removal of morbid materials of the alimentary canal, to tone up the system, increase nutrition, restore a healthy condition, rheumatism, headaches, no pep, sleeplessness, drowsiness, numbness of arms and hands, loss in weight, simple anemia and loss of color and for general weakness of the body; that the Blood and Stomach Tonic was an adequate and effective treatment for chronic blood and stomach ailments, elimination of waste materials, purification of the blood, chronic constipation, weak or nervous stomach, ulcers, and impure blood; that the Nerve Remedy For Female Disorders was an adequate and effective treatment for overcoming present weaknesses, stabilizing the changing of the female organism from puberty through menopause, headaches, dizziness, nervousness, sleeplessness, loss of appetite, pallor of the face, agonizing pain and complete nervous exhaustion; and

502(f) (1)—in that their labeling failed to bear adequate directions for use for the purposes for which they were intended;

It was alleged also that the defendant had been warned by the Food and

Drug Administration that his drugs were violative of the Act through establishment inspections, by letter, by a hearing and through two seizures of the article of drug designated as "Herb Tea" which seizures were terminated by default; and, that despite such warnings, defendant continued to violate the Act as specified above.

It was alleged further that if defendant was forced by an injunction to refrain from using the present labeling on the articles of drugs distributed by him, the said defendant would not discontinue such distribution but would, unless enjoined, continue to distribute in interstate commerce, and while held for sale after shipment in interstate commerce, such articles of drugs without labeling, or through collateral media outside of labeling. In such case, the articles of drugs would be misbranded within the meaning of Section 502(f) (1) of the Act in that their labeling would fail to bear adequate directions for use for the purposes for which they were intended.

**DISPOSITION:** Following a conference prior to a hearing on the motion for preliminary injunction on 5-26-58, the court ordered (1) that the defendant submit proposed labels and quantitative formula to the Government by mail not later than 6-2-58, and (2) that the Government thereafter comment on the proposed labels and proceed with its motion for preliminary injunction if the labels were objectionable. Subsequently, on 6-29-59, the defendant having relabeled the products, and the United States Attorney having agreed, the case was ordered dismissed by the court.

**6007. Pre-Creatine (betaine anhydrous).** (F.D.C. No. 43129. S. Nos. 38-991/2 P, 38-993/7 P.)

**QUANTITY:** 1 drum, containing 15 lbs. Pre-Creatine capsules, 108 8-oz. btl. of Pre-Creatine granules, 58 100-capsule btl. and 21 50-capsule btl. of *Pre-Creatine*, at Palo Alto, Calif.

**SHIPPED:** During 1958, the Polychemical Laboratories, Inc., shipped from New York, N.Y., to a manufacturer at San Jose, Calif., quantities of betaine anhydrous.

**LABEL IN PART:** (Drum) "Pre-Creatine Caps."; (btl.) "Granules Pre-Creatine, Lemon-Orange Flavor \* \* \* Effervescent Recommended Dosage 1 Tablespoonful \* \* \* Each Tablespoonful Contains Approx: betaine anhydrous 2 grams glycocyamine 0.5 grams," "Capsules Pre-Creatine \* \* \* Recommended Dosage 2 capsules t.i.d. Each Capsule Contains betaine anhydrous 400 mg. glycocyamine 100 mg."

**RESULTS OF INVESTIGATION:** The California manufacturer used the betaine anhydrous in the manufacture of the *Pre-Creatine* and shipped in bulk the drug so manufactured to a dealer at Palo Alto, Calif. The drugs in the bottles labeled as described above were repacked by the dealer from the bulk stock shipped to him from the California manufacturer.

**LIBELED:** 5-6-59, N. Dist. Calif.

**CHARGE:** 502(f) (1)—the labeling of the betaine anhydrous, when shipped in interstate commerce, failed to bear adequate directions for use and such article was not entitled to exemption from the requirement that its labeling bear adequate directions.

**DISPOSITION:** 9-30-59. Default—destruction.



**6008. Vibrating and massage devices.** (F.D.C. No. 41974. S. Nos. 21-829/33 P.)

**QUANTITY:** 277-device lot and 13-device lot of individually cartoned electric massage vibrating pillows, 8 individually cartoned electric *Heat-N-Vibrate Massage Pillows*, 10 individually cartoned *Dual-Salon Vibrators*, and 27 individually cartoned *Lounge-O-Matic Vibrators* at Kansas City, Mo.

**SHIPPED:** 5-27-58 and 6-2-58, from Long Island City, N.Y., by Peerless Broil-Quik Corp.

**LABEL IN PART:** (Tag) "Samson United Corp. of N.Y. \* \* \* Long Island City, N.Y."; (carton) "Peerless Electric Massage Vibrating Pillow \* \* \* Peerless Broil Quik Corp." or "11MW," "New! King Size Peerless Automatic Electric Heat-N-Vibrate Massage Pillow \* \* \* Combination 4 in 1," "Peerless Dual-Salon Vibrator" and "Peerless Lounge-O-Matic Vibrator."

**ACCOMPANYING LABELING:** Leaflets in cartons entitled "Automatic Electric Heat-N-Vibrate Massage Pillow \* \* \* Combination 3 in 1," "New! King Size Peerless Automatic Electric Heat-N-Vibrate Massage Pillow \* \* \* Combination 4 in 1," "Dual-Salon Vibrator \* \* \* How to use," and "Peerless Lounge-O-Matic Vibrator."

**RESULTS OF INVESTIGATION:** One type of vibrating pillow (277-device lot) consisted of an upholstered, corduroy-covered cushion containing a vibrating motor. Another type vibrating pillow (13-device lot) consisted of an upholstered, corduroy-covered cushion containing a vibrating motor and a heating element with a control switch. The *Heat-N-Vibrate Massage Pillow* consisted of an upholstered corduroy-covered cushion containing a vibrating motor and a high-low heating element with a control switch. The *Dual-Salon Vibrator* was an upholstered rigid frame box-type cushion containing dual vibrators and push-button controls and the *Lounge-O-Matic Vibrator* was a padded flat-type pad containing 2 controlled vibrators.

**LIBELED:** On or about 8-12-58, W. Dist. Mo.

**CHARGE:** 502(a)—when shipped, the labeling of the articles contained false and misleading representations that the articles were adequate and effective treatments for (277-device lot) relieving nervous tension, and muscular strain; (13-device lot) for relieving nervous tension, increasing circulation, reducing weight, removing excess fatty tissues and relieving muscular strain; (8-device lot) for easing nervous tension, increasing blood circulation, reducing weight, and disposing of excess fatty tissues; (10-device lot) reducing weight, for spot reducing and slenderizing the hips, stomach and thighs and for relieving muscular aches and pains susceptible to massage; and (27-device lot) relieving nervous tension, reducing weight, toning up sagging skin and firming the muscles; and 502(f)—the labeling of the article (277-device lot) failed to bear (1) adequate directions for use for the purposes and conditions for which the article was intended; and (2) such adequate warnings against use in those pathological conditions where its use may be dangerous to health, in such manner and form as is necessary for the protection of users.

**DISPOSITION:** The case was removed to the District of New Jersey for trial. Thereafter, Peerless Broil-Quik Corp., having consented, a decree of condemnation was entered on 9-30-59, and the article was ordered released under bond for relabeling.

**DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MIS-LEADING CLAIMS\***

**6009. Wonda Foot Balm and Wonda Mineral Foot and Body Bath Tablets.** (F.D.C. No. 39370. S. Nos. 38-108 M, 38-110 M.)

**INFORMATION FILED:** 9-19-57, S. Dist. N.Y., against Almo Products Corp., New York, N.Y., and William Newman, secretary-treasurer of the corporation.

**SHIPPED:** Between 1-10-56 and 2-15-56, from New York to Missouri.

**RESULTS OF INVESTIGATION:** The *Wonda Foot Balm* contained activated lanolin, menthol, eucalyptus and hexachlorophene G 11, and the *Wonda Mineral Foot and Body Bath Tablets* contained aluminum potassium-sulfate, pine oil compound, sodium bicarbonate, citric acid and eucalyptus oil.

Investigation showed that the labeling of *Wonda Foot Balm* contained false and misleading representations that it was adequate and effective for the treatment of burning sore feet and muscular soreness; that the labeling of the *Wonda Mineral Foot and Body Bath Tablets* contained false and misleading representations that the article was an adequate and effective treatment for relieving aches and pains; and that the labeling of both articles contained false and misleading representations that the articles were adequate and effective treatments for overcoming and preventing varicose veins, leg pains, pain in hips, nervousness, droop shoulder, backache, neuritis, sciatica, and pain in knees.

**CHARGE:** 502(a)—when shipped, the labeling of the articles bore false and misleading therapeutic claims and representations.

**PLEA:** Guilty.

**DISPOSITION:** 8-19-59. Corporation—\$500 fine; individual—\$400 fine.

**6010. Slim-Drin tablets.** (F.D.C. No. 43294. S. No. 56-799 P.)

**QUANTITY:** 12,000 tablets in bulk drum, and 204 25-tablet btl., and 36 100-tablet btl., at Hollywood, Fla., in possession of Vishy Drug Products.

**SHIPPED:** 3-31-59, from Philadelphia, Pa., by Richlyn Laboratories.

**LABEL IN PART:** (Drum) "Phenylpropanolamine HCL 25 Mg. \* \* \* Richlyn Laboratories, Philadelphia 24, Pa."; (btl.) "Slim-Drin Appetite Depressant Vishy Drug Products Hollywood Florida Distributor Directions: \* \* \* Each tablet contains Phenylpropanolamine Hydrochloride 25 mgm. Caution: \* \* \* Control No. 604."

**ACCOMPANYING LABELING:** (Display ctn.) "Slim-Drin For Appetite Control Just released by the Federal Government for overcounter sale."

**RESULTS OF INVESTIGATION:** The display cartons were purchased as blank cartons by the dealer and printed as needed.

The article in the bottles was repackaged by the dealer from the tablets in the bulk drum which were shipped as described above.

**LIBELED:** 7-9-59, S. Dist. Fla.

**CHARGE:** 502(a)—(drum) when shipped, the drum label of the article contained false and misleading representations that the article was adequate and effective for controlling the appetite in the management of obesity, and that it was an adequate and effective treatment for relieving asthma and bronchial spasm of the allergic type; and, while held for sale, the name "Slim-Drin" and certain statements on the bottle label and on the display carton contained

\*See also Nos. 6001, 6004-6006, 6008.

false and misleading representations that the article was an adequate and effective treatment in controlling appetite, and causing one to lose weight immediately without tough diets; and, in addition, the display cartons contained statements that the article had just been released by the Federal Government for over the counter sale and that the article contained no harmful drugs, which statements were false and misleading since it contained the drug phenylpropanolamine which is not a harmless drug; certain precautions must be observed in its use; and such drug had not been "just released" but has been available for sale without prescription for a number of years under labeling which contains appropriate restrictions on the dosage and with caution against use by individuals with high blood pressure, heart disease, diabetes, and thyroid disease, except as directed by a physician.

DISPOSITION: 11-10-59. Default—destruction.

**6011. Alfex alfalfa tablets.** (F.D.C. No. 43151. S. No. 54-869 P.)

QUANTITY: 7 drums, each containing between 22,000 and 32,000 tablets and several hundred 30-tablet, 100-tablet, and 200-tablet btl. at Philadelphia, Pa., in possession of Shane Laboratories, Inc.

SHIPPED: 3-23-59, from North Kansas City, Mo.

LABEL IN PART: (Drum) "Alfex Tablets Concentration 29,000 \* \* \* Caution: For Repackaging Use Only"; (btl.) "Alfex Hi-Potency Alfalfa Extract 400 Mg. In Each Tablet \* \* \* Distributed by Shane Laboratories, Philadelphia \* \* \* Pa."

ACCOMPANYING LABELING: Leaflets entitled "A Message of Hope for Arthritic Sufferers"; a form letter headed "Dear Pharmacist"; a window display banner reading: "Pains? Stiffness? Why Suffer? Arthritis For Relief Take Alfex Tablets"; and a newspaper advertisement used as a counter display headed "Arthritis Sufferers At Last! Amazing Fast Relief from Arthritis-Sciatica-Rheumatism-Bursitis Alfex."

RESULTS OF INVESTIGATION: The tablets in the bottle were repackaged by Shane Laboratories, Inc., from bulk drums which were shipped as described above.

LIBELED: 5-21-59, E. Dist. Pa.

CHARGE: 502(a)—while held for sale, the labeling contained false and misleading representations that the article was adequate and effective in the treatment of arthritis, rheumatism, sciatica, and bursitis.

DISPOSITION: 8-19-59. Consent—claimed by Shane Laboratories, Inc., and reworked and relabeled.

**6012. Kank-A solution.** (F.D.C. No. 43277. S. No. 63-629 P.)

QUANTITY: 36 ctns., each containing one display card of 14 vials each, and 17 ctns., each containing one display card of 28 vials each, at Boston, Mass.

SHIPPED: 5-25-59 and 6-2-59, from Plymouth, N.H., by John Arthur Geyer Co.

LABEL IN PART: (Ctn.) "One Card Kank-A \* \* \* Mr. Druggist: Recommend Kank-A," (display card) "Use Kank-A," and (vial) "Kank-A \* \* \* Contents: Myrrh, Benzoin, S.D., Alcohol."

LIBELED: 6-23-59, Dist. Mass.; amended libel 6-24-59.

CHARGE: 502(a)—when shipped, the labeling contained false and misleading representations that the article was an adequate and effective treatment for canker sores and denture sores; 502(c)—the information required by the Act to appear on the labeling, namely, the common or usual names of the active



ingredients contained therein, a statement of the quantity of contents and adequate directions for use, was not prominently placed on the vial label of the article with such conspicuousness (as compared with other words, statements, designs and devices, in the labeling), as to render such information likely to be read and understood by the ordinary individual under customary conditions of purchase and use; and 502(e) (2)—the label of the article failed to bear the common or usual name of each active ingredient contained therein, since myrrh and benzoin were not declared by their common or usual names, and the proportion of alcohol contained in the article was not declared.

DISPOSITION: 7-22-59. Consent—claimed by John Arthur Geyer Co. and relabeled.

**6013. Ree-vita tablets (vitamins).** (F.D.C. No. 43285. S. No. 56-241 P.)

QUANTITY: 3,557 30-tablet vials at Kansas City, Mo., in possession of Dr. Reeves Products, Inc.

SHIPPED: 6-7-59, from Englewood, N.J., by Zenith Laboratories.

LABEL IN PART: (Vial) "Ree-Vita One Tablet Provides: \* \* \* Distributed by Dr. Reeves' Products, Inc. Kansas City 5, Mo."

ACCOMPANYING LABELING: Letters entitled "Dear Friend."

RESULTS OF INVESTIGATION: The "Dear Friend" letters were printed locally for Dr. Reeves Products and used for promoting sales of the article.

LIBELED: 6-30-59, W. Dist. Mo.

CHARGE: 502(a)—while held for sale, the labeling accompanying the article contained false and misleading representations that the article was an adequate and effective treatment to calm nerves; eliminate "jitters"; for neuritis-like pain; for regulating the bowels; to increase pep and energy, particularly of adults over 40 years of age; for skin disorders and anemia; to restore natural color to gray hair; and to control degenerative artery disease that attacks men over 40 and women after 55 years of age.

The libel alleged also that the article was misbranded under the provisions of the law applicable to foods, as reported in the notices of judgment on foods.

DISPOSITION: 7-8-59. Consent—claimed by Dr. Reeves' Products, Inc., and relabeled.

**6014. Dermathricin Aerospray.** (F.D.C. No. 43035. S. No. 45-612 P.)

QUANTITY: 186 3-oz. cans and 217 6-oz. cans at Denver Colo.

SHIPPED: 12-22-58, from Houston, Tex., by Savage Laboratories, Inc.

LABEL IN PART: (Can) "Dermathricin Aerospray \* \* \* Contains \* \* \* Tyrothricin \* \* \* Hexadienol \* \* \* Benzocaine \* \* \* P-Chloro-M-Xylenol \* \* \* and Benzethonium Chloride \* \* \* Distributed by Arendt Laboratories, Denver 10, Colorado."

LIBELED: 5-29-59, Dist. Colo.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for all types of burns, and all bacterial, viral, and fungus infections of skin, rectum, and vaginal mucosa.

DISPOSITION: 9-28-59. Consent—claimed by Arendt Laboratories, Denver, Colo., and relabeled.

**6015. Lecitabs lecithin tablets.** (F.D.C. No. 43326. S. No. 52-096 P.)

QUANTITY: 81 90-tablet btl., 91 180-tablet btl., and 36 540-tablet btl., at Minneapolis, Minn., in possession of Pavo Co.

SHIPPED: Between 2-18-59 and 5-12-59, from Chicago, Ill., by National Lecithin, Inc.

LABEL IN PART: "National Lecitabs Lecithin Tablets A Natural Food Product Highly concentrated, extra-rich, soya Lecithin formula of 95% oil-free Phosphatides. Ingredients: Soya Lecithin, in a base of non-fat, dry milk solids and soy protein. Natural flavoring added. Dist. by: National Lecithin, Inc. 2938 N. Halsted St., Chicago 14, Ill. Indicated as a Dietary Supplement. National's Lecithin is a dietary supplement of natural lipotropic factors. This soy-based concentrate is a rich natural source of Lecithin, Cephalin, Choline and Inositol Phosphatides."

ACCOMPANYING LABELING: Leaflets entitled "National's Lecitabs \* \* \* Protect Your Heart"; "New Relief for Arthritis"; display card reading in part "Fatty Blood \* \* \* National's Lecitabs"; and banner reading in part "Fatty Blood Fat Rich Meals."

RESULTS OF INVESTIGATION: The accompanying literature was used for promotion purposes by the dealer.

LIBELED: 7-31-59, Dist. Minn.

CHARGE: 502(a)—when shipped and while held for sale, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for arthritis, rheumatism, and other rheumatic-like disorders; hardening of the arteries; lowering and normalizing cholesterol and other fatty molecules in the blood; narrowing of the arteries; high blood pressure; heart strain; pain and sickness; wide variety of ills; clogged arteries; ill health of red blood cells; improper blood coagulation; improper functioning of the brain and nervous system; neuritis; bursitis; common complaints of older folks; and heart attacks.

The libel alleged also that the article was misbranded under the provisions of the law applicable to foods as reported in notices of judgment on foods.

DISPOSITION: 11-4-59. Consent—claimed by Pavo Co. and relabeled.

**6016. Royal jelly capsules.** (F.D.C. No. 42994. S. No. 42-759 P.)

QUANTITY: 17 100-capsule btl. at Great Falls, Mont.

SHIPPED: Between 5-12-58 and 7-14-58, from New York, N.Y., by Dupree Medical Co.

LABEL IN PART: (Btl.) "Dupree Brand Natural Royal Jelly Plus \* \* \* Distributed By Dupree Medical Company, New York, N.Y., \* \* \* Each Capsule Contains: Royal Jelly 5.5 Mg. Vitamin E 5.5 Int. Units."

ACCOMPANYING LABELING: Circulars entitled "Popular Medicine March 1958 \* \* \* Royal Jelly" and poster entitled "Dupree Natural Royal Jelly."

LIBELED: 5-4-59, Dist. Mont.

CHARGE: 502(a)—when shipped and while held for sale, the labeling accompanying the article contained false and misleading representations that the article was an adequate and effective treatment for increasing life span, rejuvenating failing or wornout glandular activity, restoring vigor, eliminating a feeling of tiredness, growing hair, aiding the eyes, restoring youthful sex function to women in menopause, normalizing growth of underdeveloped children, helping ailments ranging from cancer to heart disease, stimulating

the appetite, producing a general state of well being, and improving physical appearance.

DISPOSITION: 6-30-59. Default—destruction.

**6017. Ro-Bar tablets.** (F.D.C. No. 43138. S. No. 44-788 P.)

QUANTITY: 75 60-tablet btls. at Orlando, Fla., in possession of Ro-Bar Distributors, Inc.

SHIPPED: 2-3-59, from Chicago, Ill.

LABEL IN PART: "Ro-Bar \* \* \* Active Ingredients: Bismuth Subnitrate, Lt. Magnesium Carbonate, Sodium Bicarbonate, Licorice Extract and Frangula, Calumus \* \* \* Robar Distributor \* \* \* Orlando, Florida."

ACCOMPANYING LABELING: Circulars entitled "Stomach Sufferers! Thousands Report Relief."

RESULTS OF INVESTIGATION: The circulars were printed locally for Ro-Bar Distributors, Inc.

LIBELED: 5-15-59, S. Dist. Fla.

CHARGE: 502(a)—while held for sale, the labeling accompanying the article contained false and misleading representations that the article was an adequate and effective treatment for stomach ulcers and all other painful stomach disorders.

DISPOSITION: 6-19-59. Consent—claimed by Ro-Bar Distributors, Inc., and the circulars were destroyed.

**6018. Lift.** (F.D.C. No. 42777. S. No. 47-556/7 P.)

QUANTITY: 945 1-oz. btls. at Franklin and Manchester, N.H.

SHIPPED: 8-20-58, from Boston, Mass., by Angier Chemical Co.

LABEL IN PART: "The Original Lift \* \* \* Contents: Natural Honey, Caffein, Vitamin B Combinations, 1/10 of 1% Benzoate of Soda, Peppermint Flavor. Clinical Research Foundation, Inc. \* \* \* Boston 34, Mass."

ACCOMPANYING LABELING: Leaflet in display carton entitled "Lift A safe pleasantly flavored combination of ingredients."

LIBELED: 1-5-59, Dist. N.H.

CHARGE: 502(a)—when shipped, the name of the article "*Lift*" and its labeling, contained false and misleading representations that the article was an adequate and effective treatment for giving one a "lift," making one sober, overcoming "hangover," and counteracting the effects of overindulgence in alcohol.

DISPOSITION: 7-6-59. Consent—claimed by Clinical Research Foundation, Inc., and relabeled.

**6019. Ezall Pain Reliever.** (F.D.C. No. 42218. S. No. 28-674 P.)

QUANTITY: 118 btls. at Monroe, La.

SHIPPED: 5-13-58, from Houston, Tex., by Therapeutic Laboratories, Inc.

LABEL IN PART: (Btl.) "Ezall \* \* \* Therapeutic Laboratories, Houston, Texas \* \* \* Ingredients: Methyl Salicylate, Spirits of Camphor, Acid Acetylsalicylic, Iso-propyl Alcohol \* \* \* 4 Fluid Ounces."

RESULTS OF INVESTIGATION: Analysis showed that the article contained 10 percent methyl salicylate and all the other ingredients listed on its label.

LIBELED: 10-8-58, W. Dist. La.



**CHARGE:** 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for arthritis, bursitis, rheumatism, headache, stiff neck, chest colds, croup, lumbago, neuritis, and neuralgia.

**DISPOSITION:** Therapeutic Laboratories, Inc., claimant, filed an answer denying that the article was misbranded. Thereafter, upon motion of the claimant for the removal of the case to a district of reasonable proximity to claimant's place of business, an order was entered on 3-3-59 for the removal of the case to the Eastern District of Texas. Written interrogatories were thereafter served upon the claimant, and upon claimant's default in answering such interrogatories the court entered a decree of condemnation and destruction on 10-27-59.

**6020. Vitamin and mineral capsules.** (F.D.C. No. 43283. S. No. 63-656 P.)

**QUANTITY:** 2 ctns. containing 26,500 capsules in bulk, and 88 30-capsule unlabeled vials, and 34 30-capsule labeled vials, at Holyoke, Mass., in possession of Vitamin Center.

**SHIPPED:** The vitamin capsules were shipped in bulk, on 3-17-59, from Newark, N.J.

**LABEL IN PART:** (Ctn.) "Vitamin Center Formula #76"; (vial) "Vitamin Center 30 capsules FORMULA #76 Vitamin A \* \* \* 12,500 USP Units 312% Vitamin D \* \* \* 1,000 USP Units 250% Vitamin B-1 \* \* \* 5 MGM 500% Vitamin B-2 \* \* \* 25 MGM 208% Vitamin B-6 \* \* \* 0.5 MGM \* \* \* Vitamin B-12 USP 1 MGM \* \* \* Vitamin C \* \* \* 75 MGM 250% Niacinamide USP 40 MGM 400% Calcium Pantothenate 4 MGM \* \* \* Vitamin E \* \* \* 2 I.U. \* \* \* Folic Acid USP 0.5 MGM \* \* \* DiCalcium Phosphate (A) 260 MG Calcium 75 MGM 10% Phosphorus 58 MGM Choline Bitartrate 31.4 MG Inositol 15 MG Di-Methionine 10 MG Ferrous Sulphate USP 102 MG Iron 30 MGM Cobalt Sulphate 0.193 MG Cobalt 0.04 MGM Copper Sulphate 1.257 MG Copper 0.45 MGM Magnesium Sulphate 1.573 MG Manganese 0.5 MGM Sodium Molybdate 0.253 MG Molybdenum 0.1 MGM Potassium Iodide USP 0.099 MG Iodine 0.075 MGM Potassium Sulphate 4.458 MG Potassium 2 MG Zinc Sulphate 1.388 MG Zinc 0.5 MGM Magnesium Sulphate 21.583 MG Magnesium 3 MGM \* \* \* Vitamin Center, Granby, Mass."

**ACCOMPANYING LABELING:** A guaranty card; leaflets entitled "The Magic Power" and "Yours for Good Health"; and form letters on the letterhead of the Vitamin Center plant, Granby, Mass., beginning with the words "Dear Friend: It is gratifying to know," "Dear Friend: If I could have had breakfast with you," "Dear Friend: We appreciate the opportunity"; and a number of loose vial labels.

**RESULTS OF INVESTIGATION:** The article in the vials was repacked by Vitamin Center from the bulk stock which was shipped as described above. The above-mentioned accompanying labeling was prepared by Vitamin Center.

**LIBELED:** 6-29-59, Dist. Mass.

**CHARGE:** 502(a)—while held for sale, the labeling of the article contained false and misleading representations that use of the article would produce general good health, vigor, greater and youthful energy, and zest for living; nourish and revitalize the body; develop stronger resistance to infection and colds, strength, and vitality; result in metabolism of fats and proper function of the liver; build and strengthen the blood and help nourish the organs of the body;

prevent muscle deterioration and tooth decay; result in staying young, retaining youthful pep and vigor, and growth; build strong bones and teeth, firm flesh, and develop rich, red blood; maintain health and energy; develop physical powers which wane in later years when metabolism slows down and assimilation of nutrients is improper; produce healthy skin and tissue, healthy nerves, and healthy nerve tissue; strengthen blood vessels, result in normal reproduction because it contains the sex vitamin, vitamin E; and, further, that the article was an adequate and effective treatment for and preventive of rundown feeling and tiredness; aches and pains; nervousness and depression; lowered resistance to disease; listlessness, loss of pep, headache, irritability to cope with the strain, stress and tension of everyday living; digestive upsets, dyspepsia, loss of weight, constipation, diarrhea, loss of appetite, palpitations, breathlessness, dizziness, anemia and neuritis; sinusitis, ear infections, poor vision, conjunctivitis, hypertension, roughened skin, impairment of muscular tissue, spastic colon, skin lesions, impairment of eye tissues, loss of hair, poor healing, skin troubles, nervous disorders, sore receding gums, bleeding, and loosening of teeth, soreness of joints, lowered resistance to tuberculosis, and stomach and intestinal disturbances.

The article was also alleged to be misbranded under the provisions of the law applicable to food as reported in notices of judgment on foods.

DISPOSITION: 9-14-59. Default—delivered to a public institution.

**6021. Vitamin products.** (F.D.C. No. 43554. S. Nos. 65-136/9 P.)

QUANTITY: 5 ctns., each containing 3 120-tablet btl. of *Eden Food Supplement*, 58 tins of *Eden High Protein Wafers*, 40 tins of *Eden Treat*, and 14 16-oz. cartoned btl. of *Eden Chlorophyll Solution*, at Salt Lake City, Utah.

SHIPPED: Between 5-8-59 and 7-6-59, from Sun Valley, Calif., by Garden of Eden Co.

LABEL IN PART: (Ctn. and btl.) "Eden Food Supplement A high potency Organic or Natural source dietary food supplement \* \* \* The Garden of Eden Company \* \* \* Sun Valley, California 10249"; (tin) "Contents 180 Wafers \* \* \* Eden High Protein Energy Wafers"; (tin) "Eden Treat \* \* \* From the Garden of Nature's Laboratory \* \* \* Contents: 16 ounces"; and (btl.) "16 Oz. \* \* \* Eden 100% Pure Chlorophyll Solution Each tablespoonful (15 cc) contains 100 milligrams pure chlorophyllins."

ACCOMPANYING LABELING: Phonograph records, side 1, "Nutritional Forum" and side 2, "Opportunity Knocks"; booklets entitled "Nutritional Forum Text Questions and Answers," "Opportunity Knocks," and "Your Guidebook to Better Living"; reprints from "Modern Nutrition June, 1958," and from "Reader's Digest" entitled "The Vitamins, The Food and Dr. Spies"; leaflets entitled "Why Feel Old?," "A Report on the Health of the Nation," "Let Me Put You Into Your Own Fast-growing business," "Hidden Hunger," "Eden Food Supplement," "High Protein Energy Wafers," "Eden Chlorophyll Solution," and "Eden Treat"; and starter kits containing promotional statements.

LIBELED: 9-28-59, Dist. Utah.

CHARGE: 502(a)—when shipped and while held for sale, the labeling which accompanied the article contained false and misleading representations that the Food Supplement was adequate and effective in the treatment or prevention of listless feelings; wornout feelings; unhealthy symptoms; ill health; dry skin; sallow looks; infection; fatigue; lethargy or weakness; hypersensitivity to noise; distorted heart rhythm; skin spots or inflammation; burning



or itching of eyes; digestive upsets; muscular weakness; nervous tension; loss of weight; depression; loss of muscle tone; loss of hearing; irritation of gums; nausea; loss of normal dexterity; diarrhea; fear complex; neuritis; swelling and redness of tongue; secondary anemia; poor blood coagulation; muscle cramps; lowered body efficiency; sinus infections and colds; poor fat metabolism; dim night vision; emotional irritability; convulsions; mental confusion; growth disturbances; nasal hemorrhage; dental caries; middle ear infections; dizziness; constipation; rough, dry hair and skin; headaches; insomnia; sores on corners of lips; eyes sensitive to light; slow healing cuts; arthritis pains; chronic diseases and degenerative conditions; physical and mental defects; paroxysmal convulsive disorders; cancer; collagen diseases, including arthralgias, arthritis, erythematous of purpuric skin lesions and visceral lesions, especially heart and renal; coronary thrombosis; atherosclerotic heart disease; alcoholism; infantile eczemas; hemiplegia; cerebral hemorrhage; arteriosclerosis; hypertension; liver and kidney disease; cerebral palsy; multiple sclerosis; infantile paralysis; muscular dystrophy; nephrosis; diabetes; tuberculosis; deafness; blindness due to arteriosclerosis; cataract; glaucoma, and congenital conditions; colds and virus infections; mentally retarded children; mental disease in adults; allergies; overweight; juvenile delinquency; premature aging; irregular heart rhythm; and offensive toxins and poisons from the intestines; and that the article would be effective to provide a softer complexion and youthful hands; promote growth; normalize the glands; coagulate the blood; promote normal appetite; improve circulation; promote general well-being and vigor; aid digestion; nourish brain cells; increase alertness; and normalize hemoglobin; that the article of High Protein Energy Wafers was adequate and effective in the treatment and prevention of tired and rundown feelings, protein starvation and loss of strength and energy; wrinkled faces and necks; hypoproteinemia; anemia; disorders, including toxemia, elevation of blood pressure, and edema during pregnancy; diseases of kidney and liver; liver cirrhosis; peptic ulcers; to heal wounds; chronic diseases of the colon; and that the article would be adequate and effective to build and maintain strong, healthy, vigorous bodies and minds; rich blood for young and old alike; reduce weight; to increase life expectancy; keep young; renew zest, endurance, pep and vitality; promote greater interest in life; regulate stomach acid; produce more antibodies to destroy invading bacteria and viruses; increase calcium absorption during lactation; resist infection; and heal wounds; that the Eden Treat was adequate and effective in the treatment and prevention of excessive irritability; convulsive seizures; subclinical nervous conditions; stress conditions; infections and diseases; burns; anemia; lack of energy; and that the article would be effective to develop brighter, happier, stronger and healthier children; promote vigor and health of every cell of the human body and proper growth and development; and develop strong teeth and bones; and that the Chlorophyll Solution was adequate and effective in the treatment and prevention of open wounds; minor burns; skin irritations; leg ulcers; bleeding gums and mouth infections; internal and external infections; nasal and sinus infections; body odors; bad breath; high blood pressure and other conditions of poor health; and anemias; and that the article would be adequate and effective to increase resistance to infection; produce red blood; strengthen and increase the resistance of body cells; combat and inhibit growth of bacterial invaders; raise the oxygen content; and act as a tonic.



The libel alleged also that the articles were misbranded under the provisions of the law applicable to foods as reported in notices of judgment on foods.

DISPOSITION: 2-5-60. Default—5 btls. of the Food Supplement, 5 tins of High Protein Energy Wafers, 5 tins of Eden Treat, and 3 btls. of Chlorophyll Solution were delivered to the Food and Drug Administration. The remainder of the articles were destroyed.

6022. Various medicinal herbs and drugs. (F.D.C. No. 42795. S. Nos. 13-906/58 P.)

QUANTITY: The following quantities of the articles were in possession of the W. E. B. Chemical & Products Co., Detroit, Mich.:

(Repackaged drugs) 17 1-oz. pkgs. and 1 1-gal. jar of *External Cataract Devil Shoestring*; 17 1-oz. pkgs. and 3 1-gal. jars of *Internal Cataract Herb Tea*; 23 4-oz. pkgs. and 1 1-gal. jar of *Rupture Herb Tea*; 15 1½-oz. pkgs. and 2 1-gal. jars of *Glad Herb Tea*; 30 1½-oz. pkgs. of *Pleurisy Herb Tea*; 22 1-oz. pkgs. and 1 1-gal. jar of *Appendicitis Herb Tea*; 19 1½-oz. pkgs. and 1 1-gal. jar of *Kidney Herb Tea*; 26 1½-oz. pkgs. and 1 1-gal. jar of *Varicose Veins Herb Tea*; 15 2-oz. pkgs. and 5 1-gal. glass jars of *Diabetes Herb Tea*; 23 1½-oz. pkgs. and 1 1-gal. jar of *Mountain Balm for Shingles*; 24 1½-oz. pkgs. and 1 1-gal. jar of *Asthma Herb Tea*; 25 1-oz. pkgs. and 2 1-gal. jars of *Hemorrhage Tea*; 19 1½-oz. pkgs. and 1 1-gal. jar of *Epilepsy Tea*; 20 1-oz. pkgs. and 1 1-gal. jar of *Gallstone Herb Tea*; 17 1-oz. pkgs. and 2 1-gal. jars of *Flu Herb Tea*; 24 4-oz. pkgs. of *Arthritis Herb Tea*; 21 1½-oz. pkgs. and 1 1-gal. jar of *Muscular Herb Tea*; 17 1½-oz. pkgs. and 2 1-gal. jars of *Change-of-Life Herb Tea*; 28 5-oz. pkgs. of *Gruel For Stomach*; 34 ½-oz. btls. of *Creosote for Lung Conditions*; 22 4-oz. btls. of *Blood Circulation Herb Tonic*; 123 4-oz. btls. of *Dropsy Tonic*; 8 4-oz. btls. of *Kidney Herb Tonic*; 15 4-oz. btls. of *High Blood Pressure Tonic*; 90 4-oz. btls. of *Brain Herb Tonic*; 13 4-oz. btls. of *Liver Tonic*; 47 ½-oz. btls. of *Ethyl Nitre Spirits for Prostate Trouble*; 104 4-oz. btls. of *A Blood Purifier Herb Tonic*; 122 4-oz. btls. of *Hardening of the Arteries Tonic*; 81 4-oz. btls. of *Eczema Tonic*; 89 4-oz. btls. of *Heart Tonic*; 82 4-oz. btls. of *New Life Tonic*; 102 3-oz. btls. of nasal spray *For Sinus*; 116 3-oz. btls. of *Rheumatism Herb Tonic*; 52 4-oz. btls. of *Special Blood Tonic No. 2*; 118 4-oz. btls. of *Prostate Gland Tonic*; 82 3-oz. btls. of *Golden Seal Tonic*; 28 4-oz. btls. of *Special Blood Tonic*; 136 4-oz. btls. of *Marvelous Nerve Tonic*; 117 4-oz. btls. of *Hemorrhage Tonic*; 65 1-oz. jars of *Pile Ointment*; 11 25-capsule btls. of *Reducing Capsules*; 28 3-oz. btls. of a drug to stop smoking habit; 64 4-oz. btls. of *Special Compound*; a number of 2-lb. glass jars of the following: turtlebloom or balmony, woodbetony, bugleweed, wintergreen, Queen of the Meadow, burdock, Black Root, Roman Chamomile, Cramp Bark, beech bark, Columbo, Mexican Damiana, catnip, nip or mint blossoms, fenugreek, bearberry, fragrant valerian, juniper berries, licorice root, witch-hazel, goldenseal, mandrake, plantain, ladyslipper, pleurisy or butterfly weed, marshmallow root, Black Willow Bark, shepherds-purse, wild carrot herb, devils-shoestring, wahoo, kelp, cubeb, hops, lobelia, sassafras, pokeroor, Queen's Root, black cohosh, gentian, Scullcap, Gravel Plant, Corn Silk, mistletoe, yellow dock, rupturewort, saw-palmetto, comfrey root, elder flowers, Governadora, agrimony, kola nuts, sea wrack, yerba-santa, fig-wort, broom tops, chestnut leaves, skunk cabbage.

(Bulk drugs) 3 4-lb. bags of red clover or wild clover; 1 ½-lb. bag of boneset; 1 ½-lb. bag of bloodroot, cut; 1 4-lb. bag of periwinkle; 1 1-lb.

bag of pareira brava; a number of 2-lb. jars of American Sarsaparilla Root, beech leaves and senna leaves; 2 2-lb. jars of plantain herb or alfalfa seed; 1 btl. of Creosote N.F.; 1 btl. of aloes cape, and 1 btl. of sweet spirit of nitre.

SHIPPED: Some articles, between 10-4-57 and 9-11-58, and others on unknown dates, from Indiana, California, Illinois, Missouri, and New York.

LABEL IN PART: (Pkg. or jar) "External Cataract Devil Shoestring \* \* \* W.E.B. Chemical & Products Co."; "Internal Cataract Herb Tea Contains: Roman Camomile"; "Rupture Herb Tea Contains: Comfrey, Mistletoe, Marshmallow, Rupturewort"; "Gland Herb Tea Contains: American Sarsaparilla, Blue Flag"; "Pleurisy Herb Tea Contains: Pleurisy Root"; "Appendicitis Herb Tea Contains: Elder Flowers, Peppermint, and Marshmallow"; "For Stone in the Kidney Herb Tea Queen of the Meadow, Wild Carrot, Slippery Elm, Cubeb"; "Varicose Veins Herb Tea Contains: Comfrey, Turtlebloom, Rupturewort"; "Diabetes Herb Tea Periwinkle, Great Nettle, Wintergreen, Beech Bark"; "For Shingles Contains: Mountain Balm"; "Asthma Herb Tea Contains: Cramp Bark, Skunk Cabbage, Yerba Santa"; "Hemorrhage Tea Witch Hazel Leaves"; "Epilepsy Tea Contains: Meadow, Holly Herb, Honeysuckle"; "Gallstone Herb Tea Contains Gobernadora"; "Flu Herb Tea Elder Flowers, Peppermint, Boneset"; "Arthritis Herb Tea Contains: Alfalfa Seed"; "Muscular Herb Tea Contains: Saw Palmetto"; "Change-of-Life Herb Tea Contains: Scullcap, Wood Betony, Fragrant Valerian, Hops, Lady Slipper, Chestnut leaves"; "Gruel For Stomach. Slippery Elm, Brown Sugar, Kelp, Fenugreek"; "Used for Lung Conditions. Creosote (Warning) Poison"; "Blood Circulation Herb Tonic Contains: Red Clover and American Sarsaparilla"; "Dropsy Tonic. Broom Tops, Wahoo"; "Kidney Herb Tonic. Contains: Shepherd's Purse, Wild Carrot, Gravel Plant, Agrimony, Dog Grass, Corn Silk, Cubeb, Bearberry, Juniper Berries, Parieva Brava, Marshmallow, Queen of the Meadow"; "High Blood Pressure Tonic. Contains: Red Clover, Stinging Nettle, Figwort"; "Brain Herb Tonic. American Sarsaparilla, Lousewort"; "Liver Tonic. Contains: Black Root, Mandrake, Hops, Boneset, Wahoo, Columbo Root, Wood Betony, Gentian Root, Turtlebloom"; "For Prostate Trouble. Contains: Ethyl Nitre Spirits"; "A Blood Purifier Herb Tonic. Contains: Burning Bush, Red Clover, American Sarsaparilla and Golden Seal"; "Hardening of the Arteries Tonic. Fragrant Valerian, Linden, Wood Betony, Roman Motherwort"; "Eczema Tonic. Yellow Dock, Spignet, Burdock, Poke Root"; "Heart Tonic. Gypsywort"; "New Life Tonic. Contains: American Sarsaparilla, Sasafras, Gentian Root, Tree of Life, Senna Leaves, Burdock, Licorice Root"; "For Sinus. Contains: Sodium Borate, Sodium Chloride, Camphor, Peppermint, used as a nasal spray"; "Rheumatism Herb Tonic. Contains: Black Cohash, Prickly Ash Berries, Prickly Ash Bark"; "Special Blood Tonic No. 2. Contains: Red Clover, Mandrake, Queen's Root, Black Willow, Blood Root, Golden Seal, and Sodium Benzoate,  $\frac{1}{4}$  of 1%"; "Prostate Gland Tonic. Contains: Ripple Grass"; "Golden Seal Tonic. Contains: Golden Seal"; "Special Blood Tonic. Contains: Red Clover, Mandrake"; "Marvelous Nerve Tonic. Contains: Saw Palmetto, Mexican Damiana, Kola Nut"; "Hemorrhage Tonic. Witch Hazel Leaves"; "Pile Ointment. Contains: Lanolin, Plantain, Mutton Tallow"; "Reducing Capsules. Contains: Seawack, Gentian, Columbo, 2 Grams Potassium Iodine USP, Spearmint"; "To Stop Smoking Habit. Contains: Alois Cape"; "Special Compound. Contains: Lobelia, Burdock, Blood Root"; "Turtlebloom or Balmomy"; "Wood

Betony"; "Bugle Weed"; "Wintergreen"; "Queen of the Meadow"; "Burdock"; "Black Root"; "Roman Chamomile"; "Cramp Bark"; "Beech Bark"; "Colombo"; "Mexican Damiana"; "Catnip, Nip or Mint Blossoms"; "Fenugreek"; "Bearberry"; "Fragrant Valerian"; "Juniper Berries"; "Licorice Root"; "Witch Hazel"; "Golden Seal"; "Mandrake"; "Plantain"; "Lady Slipper"; "Pleurisy or Butterfly Weed"; "Marshmallow Root"; "Black Willow Bark"; "Shepherd's Purse"; "Wild Carrot Herb"; "Devil Shoestring"; "Wahoo"; "Kelp"; "Cubeb"; "Hops"; "Lobelia"; "Sassafras"; "Poke Root"; "Queen's Root"; "Black Cohosh"; "Gentian"; "Scullycap"; "Gravel Plant"; "Corn Silk"; "Mistletoe"; "Yellow Dock"; "Rupturewort"; "Saw Palmetto"; "Comfrey Root"; "Elder Flowers"; "Gobernadora"; "Agrimony"; "Kola Nuts"; "Sea Wrack"; "Yerba Santa"; "Figwort"; "Broom Tops"; "Chestnut Leaves"; "Skunk Cabbage"; "Red Clover or Wild Clover (*Trifolium Pratense*)"; "Boneset (*Eupatorium Perfoliatum*, Aster Family)"; "Blood Root, cut"; "Periwinkle, cut"; "Pareira Brava (*Chondrodendron Tomentosum*)"; "American Sarsaparilla Root, cut"; "Beech Leaves"; "Senna Leaves"; "Plantain Herb, cut"; "Alfalfa Seed, whole"; "Creosote N.F."; "Aloes Cape U.S.P. Powdered"; and "Sweet Spirit of Nitre Ethyl Nitrite Spirit N.F."

**RESULTS OF INVESTIGATION:** The articles were shipped in bulk as described above and then were repackaged and labeled by W.E.B. Chemical & Products Co.

**LIBELED:** 1-26-59, S. Dist. Mich.

**CHARGE:** 502(a)—while held for sale, the labeling of the articles contained false and misleading representations and suggestions that the articles were an adequate and effective treatment for internal and external cataracts, ruptures, improperly functioning glands; pleurisy; appendicitis; kidney stones; varicose veins; diabetes; shingles; asthma; hemorrhages; epilepsy; gallstones; flu; arthritis; gout; wasting diseases; menopause and menstrual irregularities and pain; catarrhal infections of digestive and urinary tract; ulcerated stomach; diseases involving mucous membranes; lung conditions; impaired blood circulation; dropsy; irritated and inflamed urinary tract; high blood pressure; pain in the head, brain trouble, and "other complaints"; inactive liver; prostate trouble; impure blood; hardening of the arteries; eczema; skin eruptions; heart disease; lack of pep and vigor; sinus conditions; piles; lack of vitality and strength; in overweight conditions; overcoming the smoking habit; and constipation.

**DISPOSITION:** 7-13-59. Default—destruction.

**6023. Mineral water.** (F.D.C. No. 35395. S. Nos. 62-733 L, 62-735 L.)

**QUANTITY:** 353 cases, 6 ½-gal. btls. each, and 81 5-gal. carboys, at Memphis, Tenn., in possession of Mountain Valley Distributors (Mountain Valley Water Co.).

**SHIPPED:** 6-3-53 and 7-24-53, from Hot Springs, Ark., by Mountain Valley Spring Co.

**LABEL IN PART:** (Btl.) "Mountain Valley Mineral Water \* \* \* A naturally pure mildly-alkaline mineral water. \* \* \* it is ideal for regular use by children and adults \* \* \* Visitors in Hot Springs, Ark., usually drink at least 8 glasses each 24 hours \* \* \* Bottled by Mountain Valley Spring Co., Hot Springs, Arkansas."



ACCOMPANYING LABELING: Pamphlets entitled, "Your Health Begins With Nature," "The Importance of Mountain Valley Water in Arthritic and Rheumatic Disorders," "The Importance of Mountain Valley Water in Kidney and Bladder Disorders," "Mountain Valley Water from Hot Springs, Arkansas, in Pregnancy and Care of Children," "The Story of Mountain Valley Mineral Water from Hot Springs, Arkansas," "Is Your Trouble Mineral Deficiency?," "Facts About Mountain Valley Mineral Water from Hot Springs, Arkansas," "Why Everyone Should drink Two Quarts of Water Each Day," "Helping to Stay Young Through Minerals," and "How Much Mountain Valley Mineral Water Should I Drink?"

LIBELED: 8-19-53, W. Dist. Tenn.

CHARGE: 502(a)—when shipped and while held for sale, the accompanying labeling of the article contained false and misleading representations that drinking of Mountain Valley Mineral Water as directed (8, seven- to eight-ounce glasses daily) constitutes an adequate and effective treatment for kidney disorders, kidney and bladder stones with persistent albuminuria and pyuria, pain following bladder operations, bladder conditions or disorders, urinary tract symptoms, cystitis, pyelitis, nephritis, urethritis, arthritis, rheumatism, neuritis, conditions giving rise to excess gastric acidity and indigestion, stomach ulcers, stomach disorders, faulty metabolism, tetany due to chronic diarrhea or disturbances of the parathyroid glands, chronic fatigue, nervous tension, aches and pains and mental sluggishness; that its use would insure good health, increase benefits the body obtains from such medicines as penicillin, insulin, and sulfonamide drugs, render the urine alkaline, eliminate irritating substances and toxic wastes in the system, insure proper kidney function during pregnancy, and prevent uremic poisoning during pregnancy.

The libel alleged also that the article was misbranded under the provisions of the law applicable to foods as reported in notices of judgment on foods, No. 26597.

DISPOSITION: The legal proceedings that occurred after the filing of the libel resulting in the entry of a decree of condemnation and destruction on the basis that the article was misbranded as a food, are reported in notices of judgment on foods, No. 26597.

**6024. Buimassor massage device.** (F.D.C. No. 43345. S. No. 70-243 P.)

QUANTITY: 12,826 individually cartoned devices at York, Pa.

SHIPPED: The article was imported by Institute de Synthese Bio-Esthetique, from Paris, France, and was shipped from Baltimore, Md., by R. G. Hobelman & Co., Inc., between 3-25-59 and 4-20-59, to Pennsylvania.

LABEL IN PART: (Ctn.) "Buimassor Clinic, Par Le Massage, Giratorie En Vadure, Successives."

ACCOMPANYING LABELING: Leaflets in carton entitled "Madam Et Mademoiselle:" and "A Thousand Year-Old Hindoo Method."

RESULTS OF INVESTIGATION: The article consisted of a plastic container (coral-colored bottom and ivory-colored top), in which 10 boxwood balls are inserted to a depth of more than one-half the diameter of the balls which rotate freely and easily in any direction with very little pressure. A plastic ivory-colored snap-on strap for rolling the device on one's back was enclosed with each device in an ivory-colored zippered plastic carrying case.

**LIBELED:** 8-11-59, M. Dist. Pa.

**CHARGE:** 502(a)—when shipped and while held for sale, the labeling which accompanied the article contained false and misleading representations that the article was an adequate and effective treatment of overweight; repropotioning the entire body; that it caused wave-like stimuli to penetrate the tissue and circulate fresh, lively blood; that it improved the appearance and vitality; that it literally “melts away” all fat quickly and causes fatty areas to disappear painlessly and simply, benefiting one’s health and restoring beauty, freshness, and youthfulness; would free one’s nervous center and eliminate fatigue; that use of the device over the abdominal area would banish constipation, stimulate and condition the intestinal reflexes, and eliminate toxins which poison the bloodstream; that it would banish headaches, a sallow complexion, rheumatic ailments and prevent premature aging; and that it would cause one to feel more peppy with lots more vim and vigor.

**DISPOSITION:** 10-21-59. Consent—claimed by Bio-Aesthetic Co. of America, Inc., York, Pa., and relabeled.

**6025. Dynamic Massager and Tranqua Lounger.** (F.D.C. No. 41975. S. Nos. 3-412/5 P.)

**QUANTITY:** 35 *Dynamic Massager* devices and 7 *Tranqua Lounger* devices at Norfolk, Va.

**SHIPPED:** Between 5-12-58 and 6-10-58, from New York, N.Y., by Dynamic Mfg. Corp.

**LABEL IN PART:** (Dynamic Massager or Dynamic Home Massager) “Dynamic Manufacturing Corporation, New York, N.Y. Style 21” [or “Model M”] and “Tranqua Lounger, Model 21” [or “Model M”].”

**ACCOMPANYING LABELING:** Leaflets entitled “How the Amazing Dynamic Massager,” “A New Way to a New You,” and “Editorial Medical Men Approve Massage.”

**LIBELED:** 8-8-58, E. Dist. Va.

**CHARGE:** 502(a)—when shipped and while held for sale, the labeling which accompanied the articles contained false and misleading representations that the “*Dynamic Massager*” was an adequate and effective treatment for toning up flabby, sagging stomach muscles for that slim, smart silhouette; obesity; arthritis; nervous tension; heart disease; insomnia; cramps associated with pregnancy; anemia; lumbago; rheumatoid syndrome; angina pectoris; and fractures and paralytic conditions; and that the “*Tranqua Lounger*” was an adequate and effective treatment for easing nervous tension, deep-down relief from muscular soreness and fatigue after strenuous sports, rheumatic or arthritic-type aches, obtaining a firmer, more youthful figure, reducing heart strain, providing new vim and vigor, aiding reducing, aiding blood circulation, for obesity, arthritis, nervous tension, heart disease, insomnia, cramps associated with pregnancy, anemia, lumbago, rheumatoid syndrome, angina pectoris, and fractures and paralytic conditions; and the name “*Tranqua Lounger*” was misleading since the name suggested that the device could provide tranquillizing and other therapeutic sedation whereas it was not capable of providing such sedation; and 502(b) (1)—the “*Tranqua Lounger*” device failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor.

**DISPOSITION:** 9-4-59. Consent—claimed by Dynamic Mfg. Corp., and relabeled.

**6026. Beauti-vator massage device.** (F.D.C. No. 43033. S. No. 52-250 P.)

**QUANTITY:** 102 individually cartoned devices at Minneapolis, Minn.

**SHIPPED:** 4-24-59 and 5-1-59, from St. Louis, Mo., by Beauti-vator Sales Co.

**LABEL IN PART:** (Ctn.) "Beauti-vator By Posturamic Systems, Inc., St. Louis 15 Mo. Trims Facial Contours—Tones Facial Muscles—Beautifies Complexion—Gives Relaxing Massage," (device) "Beauti-Vator By Posturamic Systems, Inc. 533 Bittner St. St. Louis 15, Mo. \* \* \* Serial 01946 [or "00492"]," (leaflet in ctn.) "Look Younger—Prettier—After 5 Minutes With Your Beauti-Vator."

**ACCOMPANYING LABELING:** Leaflets entitled "A New Beauty Experience" and sales manuals.

**RESULTS OF INVESTIGATION:** The article consisted of a padded headrest attached to a housing containing an electric motor capable of transmitting vibration-like action to a chinstrap fastened to both ends of the motor shaft.

**LIBELED:** 5-27-59, Dist. Minn.

**CHARGE:** 502(a)—when shipped, the labeling contained false and misleading representations that the article was an adequate and effective treatment for causing one to look younger and prettier; improving facial form, texture, and color; stimulating circulation; firming sagging cheek and chin tissues; eliminating lines, furrows, and excess fat, wrinkles and double chin, erasing tiny blemishes; easing nervous tension; slimming and contouring; restoring youthful complexion; replacing and revitalizing dead-looking skin; and for providing a radiant and youthful glow and appearance, and improved beauty.

**DISPOSITION:** 7-8-59. Consent—claimed by Posturamic System, Inc., St. Louis, Mo., and relabeled.

**6027. Relax-A-Lounge.** (F.D.C. No. 42236. S. No. 12-047 P.)

**QUANTITY:** 34 devices individually cartoned at Chicago, Ill.

**SHIPPED:** 10-7-58, from Los Angeles, Calif., by Relax-A-Cushion, Inc.

**LABEL IN PART:** (Ctn.) "Topper Relax-A-Lounge Health Unit \* \* \* Model L. S. Ser. No. 000490."

**ACCOMPANYING LABELING:** (Leaflet) "Topper Relax-A-Lounge 3-Way Systems Reduce at Home—Relax at Home—Health at Home.

**RESULTS OF INVESTIGATION:** The article was a box-type unit containing an electric motor capable of providing controlled vibrations of 100 to 3,000 actions per minute and fitted with tubular attachments to provide a cot-like device for applying the vibrations to an individual in a reclining position.

**LIBELED:** 10-21-58, N. Dist. Ill.

**CHARGE:** 502(a)—when shipped, the labeling contained false and misleading representations that the article was an adequate and effective treatment for rheumatism, bursitis, and arthritis; stimulating and promoting circulation; breaking down fatty tissues; relief of muscular aches and pains; relieving tension; and reducing weight without diet.

**DISPOSITION:** 7-31-59. Consent—claimed by Topper Relax-A-Lounge 3-Way Systems Reduce At Home—Relax At Home—Health At Home and Relax-A-Cushion, Inc., and relabeled.



**6028. Relaxor vibrator massager.** (F.D.C. No. 42995. S. Nos. 23-499/500 P.)

**QUANTITY:** 45 individually cartoned devices at Los Angeles, Calif.

**SHIPPED:** 1-14-59, from Chicago, Ill., by Stantex Mfg. Co., Inc.

**LABEL IN PART:** (Cover on device) "The Relaxor Vibrator \* \* \* Stantex Mfg. Co. \* \* \* Chicago, Ill."; (leaflet enclosed in cover) "The Relaxor. Vibrator Cushion."

**RESULTS OF INVESTIGATION:** Examination showed that the article was an upholstered cushion containing an electric motor providing vibration, and (10 devices) a heating element.

**LIBELED:** 5-4-59, S. Dist. Calif.

**CHARGE:** 502 (a)—when shipped, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for promoting circulation, easing nervous tension, relieving aching back, firming fatty tissues, and reducing thighs, flabbiness, and bulges.

**DISPOSITION:** 6-17-59. Default—destruction.

**6029. Nemectron device.** (F.D.C. No. 41567. S. No. 11-958 P.)

**QUANTITY:** 3 devices at Detroit, Mich.

**SHIPPED:** On an unknown date, from Lindau, Germany, by Deutsche Nemectron Gesellschaft m.b.h.

**LABEL IN PART:** (Metal tag on device) "Deutsche Nemectron Gesellschaft m.b.h. \* \* \* Lindau (B) Germany."

**ACCOMPANYING LABELING:** Leaflets entitled "Nemectron The Apparatus For Bio-Electric Treatments."

**RESULTS OF INVESTIGATION:** The article consisted of an electrical apparatus which converted household current into stimulating voltages which were applied to the human body through four applicator pads.

**LIBELED:** 5-23-58, E. Dist. Mich.

**CHARGE:** 502(a)—when shipped and while held for sale, the labeling which accompanied the article contained false and misleading representations that the article was effective for toning the body; strengthening the body; regenerating the tissues; rejuvenating the body; producing beneficial effects on the cells and tissues of the body, including the nerves, muscles, glands, and brains; overcoming the damages and ravages of age; restoring the lost elasticity of the skin; removing deposits of fat (double chin), and obnoxious toxic substances caused by impaired cellular metabolism; removing wrinkles and furrows; improving cellular metabolism; accelerating venous and lymphatic circulation, thus overcoming cellulitis and acne; "normalizing" a condition of underdevelopment of the breasts and overdevelopment of the breasts; overcoming a condition of atonic abdominal muscles; strengthening the feet; eliminating edema and infiltration of the ankle and calf; and overcoming a condition of fallen arches.

**DISPOSITION:** 10-19-59. Default—delivered to Food and Drug Administration.

**6030. Mar V Lounge device.** (F.D.C. No. 43179. S. No. 53-220 P.)

**QUANTITY:** 50 assembled devices including the component parts consisting of metal frames and canvas covers and oscillators, at Phoenix, Ariz., in the possession of Pretorius Approved Products.

**SHIPPED:** Between 2-1-59 and 5-23-59, the metal frames and canvas covers of the devices were shipped from Los Angeles, Calif., by Inco Co., and the oscillators for the devices were shipped from Los Angeles, Calif., by Crefan Motors.

**LABEL IN PART:** "Mar V Lounge, Model Marvlmatic."

**ACCOMPANYING LABELING:** Pamphlets entitled "Mar V Lounge Can Make You Look and Feel Younger Than You Are!," direction sheets entitled "The Pretorius Rx Lounge," testimonial letters dated 3-2-59 and signed by "A. L. Schram," and a number of guarantee cards.

**RESULTS OF INVESTIGATION:** The assembled device was an adjustable tubular frame, fitted with canvas to provide a cot-like device. A small electric motor, attached to a cross member of the tubular frame provided vibration to the canvas covered frame.

**LIBELED:** 7-23-59, Dist. Ariz.

**CHARGE:** 502(a)—the labeling accompanying the article, when shipped and while held for sale, contained false and misleading representations that the device was an adequate and effective treatment for slenderizing, toning and firming the muscles, trimming hips and thighs, increasing weight, overcoming back ailments, controlling weight, improving posture, overcoming tension, toning and lifting sagging tissues and relieving pain caused by tension, and congestion in the tissues.

**DISPOSITION:** 9-1-59. Consent—claimed by Martin Pretorius, Phoenix, Ariz., and relabeled.

**6031. Nemectrodyn device.** (F.D.C. No. 41868. S. No. 11-450 P.)

**QUANTITY:** 1 device at Birmingham, Mich.

**SHIPPED:** On an unknown date from Lindau, Germany, by Deutsche Nemectron Gesellschaft m.b.h.

**LABEL IN PART:** (Metal tag) "Nemectrodyn."

**ACCOMPANYING LABELING:** Leaflets entitled "Nemectrodyn Interference—Therapy (Physiotherapy)."

**RESULTS OF INVESTIGATION:** The device consisted of an electrical apparatus which converted household current into stimulating voltages which were applied to the human body through applicator pads.

**LIBELED:** 6-23-58, E. Dist. Mich.

**CHARGE:** 502(a)—when shipped and while held for sale, the labeling which accompanied the article contained false and misleading representations that the article was an adequate and effective treatment for overcoming chronic inflammatory infiltrations, relieving atonic or paralyzed muscles, overcoming ankylosis, producing a beneficial effect on the secretory and excretory glands, overcoming ptosis, hypoperistalsis, subacidity, atony of the intestines, atonic obstipation, stasis of the lymph and venous flow, atony and paresis of the striated muscle, intermittent claudication, Raynaud's disease, neuritis, neuralgia, sciatica, arthritis, rheumatism, salpingo-ovaritis, prostatitis, ulcerus ventriculi et duodeni, spastic pain, irritation of the autonomic nerve system, and for providing an analgesic sedative and spasmolytic therapy.

**DISPOSITION:** 7-30-59. Default—delivered to the Food and Drug Administration.

**6032. Trimform devices.** (F.D.C. No. 43014. S. No. 46-320 P.)

**QUANTITY:** 9 individually cartoned devices at New Orleans, La., in possession of Trimform of Louisiana, Inc.

**SHIPPED:** 3-24-59, from North Hollywood, Calif., by Wizard Trimform Sales Co., Inc.

**LABEL IN PART:** (Device) "Trimform by Wizard \* \* \* North Hollywood, Calif."

**ACCOMPANYING LABELING:** Leaflets entitled "The Miracle of Trimform" and leaflets and cards entitled "A New Discovery."

**RESULTS OF INVESTIGATION:** The cards entitled "A New Discovery" were printed locally for the dealer. The article consisted of a box-like housing enclosing an electric vibrating motor and fitted on top with an upholstered cushion through which vibrations were transmitted; removable extensions attached to either side of the motor housing comprised the "Trimform" table.

**LIBELED:** 5-19-59, E. Dist. La.

**CHARGE:** 502(a)—when shipped and while held for sale, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for spot reducing; providing a healthier life; improving posture; relieving tension and thereby eliminating the cause of many serious ailments; increasing circulation; reducing weight; maintaining body proportions for entire life; firming flabby tissues; and trimming the figure.

**DISPOSITION:** 6-26-59. Consent—claimed by Wizard Trimform Sales Co., Inc., North Hollywood, Calif., and relabeled.

**6033. Bobrich vibrator.** (F.D.C. No. 41818. S. No. 26-552 P.)

**QUANTITY:** 90 individually cartoned devices at Minneapolis, Minn.

**SHIPPED:** 5-8-58, from New York, N.Y., by Bobrich Products Co.

**LABEL IN PART:** (Ctn.) "Bobrich Salon Type Vibrator Large Professional Size \* \* \* Bobrich Products Corporation, New York, N.Y. \* \* \* Relax-Reduce-Massage-Revitalize."

**ACCOMPANYING LABELING:** Instruction sheet in each carton.

**RESULTS OF INVESTIGATION:** The article was an upholstered, solid-frame cushion, containing an electric motor providing vibration.

**LIBELED:** 6-24-58, Dist. Minn.

**CHARGE:** 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for easing nervous tension, revitalizing, reducing, increasing blood circulation, soothing aches and pains, and disposing of excess fatty tissues.

**DISPOSITION:** 7-22-58. Consent—claimed by S. S. Hollender, Inc., Chicago, Ill., and relabeled.

**6034. Relax-4-Life Vibrating Chair.** (F.D.C. No. 43032. S. No. 52-552 P.)

**QUANTITY:** 5 chairs at Minneapolis, Minn.

**SHIPPED:** 3-23-59 and 3-30-59, from Santa Rosa, Calif., by Relax-4-Life Co.

**ACCOMPANYING LABELING:** Leaflets entitled "Relax-4-Life," "Healthtone," and "Operating Instructions for Relax-4-Life Chair."

**RESULTS OF INVESTIGATION:** The article was an adjustable, reclining, upholstered chair containing polyfoam cushioning and a motor capable of providing vibrations.



**LIBELED:** 5-27-59, Dist. Minn.

**CHARGE:** 502(a)—when shipped, the labeling, namely, the above-described leaflets, contained false and misleading representations that the article was an adequate and effective treatment for relieving tension, headaches, backaches, poor circulation, arthritis, bursitis, and rheumatism; building health; and toning muscles.

**DISPOSITION:** 8-27-59. Consent—claimed by Joseph E. McCann, t/a Relax-4-Life Co., and relabeled.

**6035. Temp-rite Mattrest mattress.** (F.D.C. No. 42566. S. No. 7-879 P.)

**QUANTITY:** 4 full-size and 5 twin-size mattresses at Manchester, N.H.

**SHIPPED:** 10-21-58 and 11-4-58, and on other unknown dates, from Worcester, Mass., by Worcester Bedding Co.

**LABEL IN PART:** "Posture Quilt's Temp-rite Mattress \* \* \* Manufactured by Posture Quilt of Worcester, Massachusetts."

**ACCOMPANYING LABELING:** Placards entitled "You Will Enjoy \* \* \* Better Health"; leaflets entitled "Now! Dial the sleeping temperature you like best"; and "Relieves Arthritis-Rheumatism While you Sleep! \* \* \* Temp-rite Mattrest"; and window streamers entitled "Posture Quilt's Temp-rite Mattrest."

**RESULTS OF INVESTIGATION:** The article was similar to a conventional mattress, but contained a rheostatically controlled heating element.

**LIBELED:** 12-15-58, Dist. N.H.

**CHARGE:** 502(a)—when shipped, the labeling accompanying the article contained false and misleading representations that the article was an adequate and effective treatment for relieving arthritis, bursitis, rheumatism, and insomnia.

**DISPOSITION:** 8-25-59. Consent—the labeling was destroyed and the article was delivered to a local hospital for its use.

**6036. Relaxalon vibrating cushion.** (F.D.C. No. 42734. S. No. 18-914 P.)

**QUANTITY:** 2 individually cartoned devices at Denver, Colo., in possession of Dave Cook Sporting Goods Co.

**SHIPPED:** 1-19-59, and on an unknown date, from Huntington Park, Calif., by U.S. Chaircraft Mfg. Corp.

**LABEL IN PART:** (Device) "Relaxalon \* \* \* Huntington Park, California"; (leaflet in ctn.) "Your Guide To A Happier Life."

**ACCOMPANYING LABELING:** Display placard entitled "Relaxalon."

**RESULTS OF INVESTIGATION:** The device consisted of a box-shaped housing containing an electric motor capable of providing vibrating or oscillating motion to an upholstered cushion attached to the top of the housing.

The display placard was prepared by the dealer from a newspaper advertisement.

**LIBELED:** 3-24-59, Dist. Colo.

**CHARGE:** 502(a)—when shipped and while held for sale, the labeling of the device contained false and misleading representations that the article was an adequate and effective treatment for relieving aches, pains, and miseries; increasing blood circulation; breaking down fatty tissue; improving posture; increasing weight; reducing weight without diets; conditioning feet, head, neck, and shoulders; and slimming the hips.

DISPOSITION: 7-21-59. Default—delivered to the Food and Drug Administration.

**6037. Electric massage pillow.** (F.D.C. No. 43000. S. No. 40-257 P.)

QUANTITY: 32 cartoned devices at San Francisco, Calif.

SHIPPED: 1-14-59, from Brooklyn, N.Y., by Foremost Appliance Corp.

LABEL IN PART: (Tag on device) "Combination Heating & Vibrating Electric Massage Pillow \* \* \* Foremost Appliance Corp., B'klyn 1, N.Y."; (ctn.) "Vibrant Heat Electric Massage Pillow \* \* \* Relax and Revitalize"; (leaflet in ctn.) "Men \* \* \* Women Relax-Refresh-Revitalize with the Foremost Electric Vibrating Massage Pillow."

RESULTS OF INVESTIGATION: The article was a pillow-shaped device containing a heating element and an electric motor capable of providing vibration.

LIBELED: 5-6-59, N. Dist. Calif.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for revitalizing, rejuvenating, and reducing the body; relieving tensions; giving tone to sagging skin, and firming unsightly bulges; "spot" reducing and dispelling backache.

DISPOSITION: 8-18-59. Default—destruction.

**6038. Ultraviolet therapy lamp.** (F.D.C. No. 43167. S. No. 5-686 P.)

QUANTITY: 4 large and 2 small devices at Washington, D.C., in possession of Hecht Co.

SHIPPED: 1-31-59 and 3-4-59, from Chicago, Ill.

ACCOMPANYING LABELING: Placard entitled "Health Lamp."

RESULTS OF INVESTIGATION: The placard was prepared by Hecht Co.

LIBELED: 6-1-59, Dist. Columbia.

CHARGE: 502(a)—while held for sale, labeling accompanying the article contained false and misleading representations that the article was an adequate and effective treatment for relieving pains of arthritis, bursitis, or any muscular ailment; and that the article would provide general health and therapeutic benefits.

DISPOSITION: 7-6-59. Consent—claimed by the May Department Stores Co. by Walter E. Reits, Jr., % The Hecht Co. Div., Washington, D.C. The placard was destroyed.

**6039. Slender-belt.** (F.D.C. No. 42990. S. No. 52-053 P.)

QUANTITY: 20 individually cartoned devices at Minneapolis, Minn., in possession of Leader Furniture & Carpet.

SHIPPED: 3-26-59, from New York, N.Y., by Frank M. Katz, Inc.

LABEL IN PART: (Device) "Foremost Slender-Belt" and (booklet enclosed in cartons) "Slenderize \* \* \* Improve Your Figure \* \* \* Slender-Belt."

ACCOMPANYING LABELING: Newspaper tear sheets entitled "Help You Slenderize Stay Youthfully Slim."

RESULTS OF INVESTIGATION: The article consisted of an electric motor and housing mounted on an upright pole attached to a platform base. On each end of the motor shaft, a web-like belt was attached which was caused to vibrate.

The newspaper tear sheets were prepared by Leader Furniture & Carpet and were used as a display placard.

**LIBELED:** 4-27-59, Dist. Minn.

**CHARGE:** 502(a)—when shipped and while held for sale, the labeling contained false and misleading representations that the article was an adequate and effective treatment for slenderizing and improving the figure; reshaping the figure for better health; easing sore muscles and joints; eliminating fat deposits in specific areas of the body; and building healthy tissues.

**DISPOSITION:** 6-30-59. Default—delivered to Food and Drug Administration.

**6040. Phonograph records.** (F.D.C. No. 42933. S. Nos. 47-833/7 P.)

**QUANTITY:** 50 sets, each set consisting of a folder of 3 records each, at Windsor, Conn.

**SHIPPED:** 2-3-59 and 3-19-59, from Chicago, Ill., by Audio-Suggestion Institute, Inc.

**LABEL IN PART:** (Record) "Audio Suggestion Institute \* \* \* Pressed for Audio Suggestion Institute."

**ACCOMPANYING LABELING:** Booklet in folder entitled "Applied Home Hypno-therapy"; leaflets entitled "Are You Digging Your Own Grave?"; letterheads entitled "I hereby order and agree" and "Agents/Your Profit Schedule"; sales instructions entitled "Direct Sales Approach"; letterhead applications to become a dealer; reprints of articles from the 10-29-58, 10-28-58, and 2-2-59 issues of the Chicago Daily Tribune; reprints of article from the 8-17-58 issue of the Chicago Sun Times; reprints of article from the December 1958 issue of the Cosmopolitan magazine; reprints of portions of articles from the August 1958 issue of True Story magazine, September 1958 issue of McCall's magazine, and July 1958 issue of Science Digest magazine; reprints of a portion of 11-3-58 issue of Life magazine; reprints of letterhead entitled "Home Hypnotherapy Course/Complete course 202A \* \* \*"; reprints of portion of article from October 1956 issue of Reader's Digest magazine; reprints of testimonial letters dated 7-9-58 by Mrs. Wm. Hutchinson and 7-12-58, by Mrs. Viola Granado; reprints of article from the November issue of Popular Medicine magazine; reprints of letter to "Fred X. Stark, Pres." signed by "George B. Stone" containing ad "Can't Lose Weight?"; reprints of article from the 2-11-59 issue of the Chicago Daily News.

**LIBELED:** 4-16-59, Dist. Conn.

**CHARGE:** 502(a)—when shipped, the labeling of the article contained false and misleading representations that it was an adequate and effective treatment for improving mental health and well being; causing one to become a dynamic, vigorous personality; providing a healthier, happier, more abundant life; curing mental distress; controlling the appetite; overcoming nervous tension, headaches, insomnia, smoking habit, nail biting, indigestion, overeating, alcoholism, frigidity, impotence, cerebral palsy, bed wetting, asthmatic attacks, menopausal difficulties, paralysis of polio, tuberculosis, arthritis, sinus trouble, blindness, cancer, neurosis, ulcers, stammering, skin troubles, bad habits, and anxieties; healing wounds; curing warts; reducing or gaining weight; increasing sexual powers; and that the article would provide through "home hypnotherapy" a means of overcoming specific problems.

**DISPOSITION:** 6-19-59. Default—delivered to the Food and Drug Administration.



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	6027, 6028, 6030, 6033, 6034,	Relax-A-Lounge _____	6027
	6036	Relax-4-Life vibrating chair____	6034
Douche powder_____	6006	Relaxor vibrator massager_____	6028
Dual-Salon Vibrator_____	6008	Rem-Al Emetic_____	6001
Dynamic Massager_____	6025	Rheumatism, remedies for_____	6006,
Eden Food Supplement, Eden			6011, 6015, <sup>2</sup> 6019
High Protein Wafers, Eden		Ro-Bar tablets_____	6017
Treat, and Eden Chlorophyll		Royal jelly capsules_____	6016
Solution_____	6021	Sciatica, remedies for. <i>See</i> Rheu-	
Electric massage pillow_____	6037	matism, remedies for.	
Emmenagogue_____	6001	Skin disorders, remedies for. 6006, 6014	
Enerjol capsules_____	<sup>1</sup> 6004	Slender-belt (device)_____	6039
Ezall Pain Reliever_____	<sup>2</sup> 6019	Slim-Drin tablets_____	6010
Gallstones, remedy for_____	6006	Temp-rite Mattrest mattress____	6035
Gastric ulcers, remedy for_____	6017	Tranqua Lounger_____	6025
Gout, remedies for. <i>See</i> Rheu-		Tranquil_____	<sup>2</sup> 6005
matism, remedies for:		Tranquilizer _____	<sup>2</sup> 6005
Grisovin tablets_____	6002	Trimform devices_____	6032
Heat-N-Vibrate Massage Pillow____	6008	Ulcers, gastric, remedy for_____	6017
Herbs and drugs, medicinal_____	6022	Ultraviolet therapy lamp_____	6038
Kank-A solution_____	6012	Vitamin preparations_____	<sup>2</sup> 6003,
Laxative, without proper warn-			6013, 6020, 6021
ing statement_____	6006	Wonda Foot Balm_____	6009
Lecitabs lecithin tablets_____	6015	Mineral Foot and Body Bath	
Lift_____	6018	Tablets_____	6009
Lounge-O-Matic Vibrator_____	6008		
Lumbago, remedies for. <i>See</i>			
Rheumatism, remedies for.			

<sup>1</sup> (6004) Seizure contested. Contains opinions of the courts.<sup>2</sup> (6003, 6005, 6019) Seizure contested.

## SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

	N.J. No.		N.J. No.
Almo Products Corp.:		Hecht Co.:	
Wonda Foot Balm and Wonda		ultraviolet therapy lamp-----	6038
Mineral Foot and Body Bath		Hobelman, R. G., & Co., Inc.:	
Tablets -----	6009	Buimassor massage device-----	6024
Alva Laboratories:		Horner, Wm., Co. <i>See</i> Fictum,	
Tranquil -----	<sup>2</sup> 6005	Adolph.	
Angier Chemical Co.:		Horner, Wm. M., Co. <i>See</i> Fictum,	
Lift-----	6018	Adolph.	
Arendt Laboratories:		Ince Co.:	
Dermathricin Aerospray-----	6014	Mar V Lounge device-----	6030
Audio-Suggestion Institute, Inc.:		Institute de Synthese Bio-Es-	
phonograph records-----	6040	thetique:	
Beauti-vator Sales Co.:		Buimassor massage device---	6024
Beauti-vator massage device--	6026	Katz, Frank M., Inc.:	
Bobrich Products Co.:		Slender-belt (device)-----	6039
Bobrich vibrator-----	6033	Leader Furniture & Carpet:	
Bobrich Products Corp.:		Slender-belt (device)-----	6039
Bobrich vibrator-----	6033	Maizel Laboratories, Inc.:	
Buimassor Clinic:		vitamin B <sub>12</sub> injection-----	<sup>2</sup> 6003
Buimassor massage device-----	6024	Mountain Valley Distributors:	
Clinical Research Foundation,		mineral water -----	6023
Inc.:		Mountain Valley Spring Co.:	
Lift-----	6018	mineral water -----	6023
Crefan Motors:		Mountain Valley Water Co. <i>See</i>	
Mar V Lounge device-----	6030	Mountain Valley Distributors.	
Dave Cook Sporting Goods Co.:		National Lecithin, Inc.:	
Relaxalon vibrating cushion--	6036	Lecitabs lecithin tablets-----	6015
Deutsche Nemectron Gesellschaft		Newman, William:	
m.b.h.:		Wonda Foot Balm and Wonda	
Nemectron device-----	6029	Mineral Foot and Body Bath	
Nemectro-dyn device-----	6031	Tablets-----	6009
Dupree Medical Co.:		Overseas Pharmaceutical Co.:	
royal jelly capsules-----	6016	Drisovin tablets-----	6002
Dynamic Mfg. Corp.:		Owen Laboratories:	
Dynamic Massager and Tran-		Enerjol capsules-----	<sup>1</sup> 6004
qua Lounger-----	6025	Peerless Broil-Quik Corp.:	
Fictum, Adolph:		vibrating and massage devices--	6008
various drugs-----	6006	Personal Drug Co.:	
Foremost Appliance Corp.:		Quik Kap capsules and Rem-Al	
electric massage pillow-----	6037	Emetic-----	6001
Garden of Eden Co.:		Pavo Co.:	
vitamin products-----	6021	Lecitabs lecithin tablets-----	6015
Geyer, John Arthur, Co.:		Polychemical Laboratories, Inc.:	
Kank-A solution-----	6012	Pre-Creatine-----	6007
Glaxo Laboratories:			
Grisovin tablets-----	6002		

<sup>1</sup> (6004) Seizure contested. Contains opinions of the courts.<sup>2</sup> (6003, 6005, 6019) Seizure contested.

	N.J. No.		N.J. No.
Posturamic Systems, Inc.:		Shane Laboratories, Inc.:	
Beauti-vator massage device--	6026	Alfex alfalfa tablets-----	6011
Posture Quilt:		Stantex Mfg. Co., Inc.:	
Temp-rite Mattrest mattress--	6035	Relaxor vibrator massager----	6028
Preterior Approved Products:		State Pharmacal Co.:	
Mar V Lounge device-----	6030	Tranquil-----	<sup>2</sup> 6005
Reeves', Dr., Products, Inc.:		Therapeutic Laboratories, Inc.:	
Ree-vita tablets-----	6013	Ezall Pain Reliever-----	<sup>2</sup> 6019
Relax-A-Cushion, Inc.:		Trimform of Louisiana, Inc.:	
Relax-A-Lounge-----	6027	Trimform devices-----	6032
Relax-4-Life Co.:		U.S. Chaircraft Mfg. Corp.:	
Relax-4-Life vibrating chair--	6034	Relaxalon vibrating cushion--	6036
Rem-Al Drug Co.:		Vishy Drug Products:	
Quik Kap capsules and Rem-		Slim-Drin tablets-----	6010
Al Emetic-----	6001	Vitamin Center:	
Richlyn Laboratories:		vitamin and mineral capsules--	6020
Slim-Drin tablets-----	6010	W.E.B. Chemical & Products Co.:	
Ro-Bar Distributors, Inc.:		various medicinal herbs and	
Ro-Bar tablets-----	6017	drugs-----	6022
Savage Laboratories, Inc.:		Wizard Trimform Sales Co., Inc.:	
Dermathricin Aerospray-----	6014	Trimform devices-----	6032
Savitch, Leo:		Worcester Bedding Co.:	
Quik-Kap capsules and Rem-		Temp-rite Mattrest mattress--	6035
Al Emetic-----	6001	Zenith Laboratories:	
		Ree-vita tablets-----	6013

<sup>2</sup> (6003, 6005, 6019) Seizure contested.



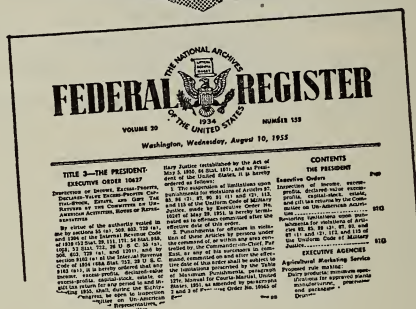
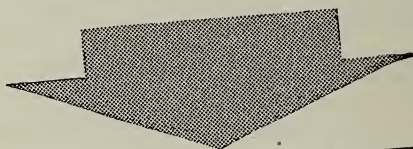


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32nd

D.D.N.J., F.D.C. 6041-6080

Issued November 1960

**U.S. Department of Health, Education, and Welfare**  
**FOOD AND DRUG ADMINISTRATION**

**NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD,  
DRUG, AND COSMETIC ACT**

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

6041-6080

**DRUGS AND DEVICES**

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were adulterated or misbranded within the meaning of the Act when introduced into and while in interstate commerce, when shipped to a holder of a guaranty, or while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings in which decrees of condemnation were entered after default or consent and (2) criminal proceedings terminated upon pleas of nolo contendere and guilty or by judgments of guilty and not guilty after trial. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation, and the criminal proceedings are against the *firms* or *individuals* charged to be responsible for violations.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D.C., November 18, 1960.

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\*For violative sale of prescription drugs, see No. 6041; drugs in violation of prescription labeling requirements, Nos. 6041, 6043; omission of, or unsatisfactory, ingredients statements, Nos. 6041, 6043, 6047, 6056; an imitation of, and sale under name of, another drug, No. 6041; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 6041, 6043; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 6041, 6043; labeling information not likely to be read and understood by the ordinary individual under customary conditions of purchase and use, No. 6043; cosmetics, actionable under the drug provisions of the Act, Nos. 6048, 6068.



SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS  
REPORTED IN D.D.N.J. 6041-6080

*Adulteration*, Section 501(b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopoeia), and its quality differed from the standard set forth in such compendium; Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength differed from or its quality fell below that which it purported or was represented to possess; and Section 501(d)(2), the article was a drug, and a substance had been substituted wholly or in part therefor.

*Misbranding*, Section 502(a), the labeling of the article was false and misleading; Section 502(b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; Section 502(c), certain information required by the Act to appear on the label or labeling was not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use; Section 502(e), the article was a drug not designated solely by a name recognized in an official compendium, and its label failed to bear (1) the common or usual name of the drug and (2) the drug was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient; Section 502(f), the labeling of the article failed to bear (1) adequate directions for use and (2) adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 502(i)(2), the article was an imitation of another drug and (3) the article was offered for sale under the name of another drug; Section 502(l), one article contained penicillin, one article contained chloramphenicol, and one article contained manganese bacitracin, and none of the articles were from a batch with respect to which a certificate or release had been issued pursuant to Section 507; and Section 503(b)(4), the article was subject to Section 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

*New-drug violation*, Section 505(a), the article was a new drug within the meaning of Section 201(p), which was introduced into interstate commerce, and an application filed pursuant to Section 505(b) was not effective with respect to such drug.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

6041. Imitation Miltown tablets and imitation Equanil tablets. (F.D.C. No. 42166. S. No. 27-359 M.)

INDICTMENT FILED: 4-22-59, S. Dist. N.Y., against Seymour Blau, Ludwig Spandau, and Salude Laboratories, Inc., New York, N.Y.

ALLEGED VIOLATION: The indictment alleged that the defendants, with intent to defraud and mislead, caused to be introduced into interstate commerce, quantities of *imitation Miltown tablets* and *imitation Equanil tablets* containing meprobamate, which were new drugs and were adulterated and misbranded.

The indictment alleged also that from May 1, 1957 to the filing of the indictment the defendants did conspire, combine, confederate, and agree together and with other persons to violate 301(a) and 301(d) of the Act, and that it was a part of such conspiracy that the defendants, with intent to defraud and mislead, would unlawfully cause the above-mentioned tablets to be introduced into interstate commerce without effective new drug applications and in an adulterated and misbranded condition.

It was alleged further that in pursuance of the conspiracy and to effect the objects thereof the following overt acts were committed: that Ludwig Spandau, about July 1957, caused a number of *imitation Miltown tablets* and *imitation Equanil tablets* to be fabricated and to be packaged in unlabeled bottles and the bottles to be packed in cartons; that, on 7-30-57, Ludwig Spandau and Seymour Blau caused the tablets to be transported to the 34th St. Greyhound Bus Terminal, New York, N.Y.; that during the transportation of the tablets to the bus terminal, Seymour Blau affixed address stickers to the cartons; and that Seymour Blau delivered the tablets to the baggage room at the 34th St. Greyhound Bus Terminal.

**CHARGE:** 501(c)—when shipped, the quality of the tablets fell below that which they purported and were represented to possess since they contained less than 400 milligrams of meprobamate per tablet; 502(b)—the labels of the tablets failed to bear (1) the name and place of business of the manufacturer, packer, or distributor and (2) an accurate statement of the quantity of contents; 502(e) (1)—the labels of the tablets failed to bear the common or usual name of the drug; 502(f) (1)—the labeling of the tablets failed to bear adequate directions for use; 502(i) (2)—the tablets were imitations of other drugs, namely, Miltown and Equanil; 502(i) (3)—the articles were offered for sale under the name of other drugs, namely, Miltown and Equanil; and 503(b) (4)—the tablets were subject to 503(b) (1) and their labels failed to bear, prior to dispensing, the statement "Caution: Federal law prohibits dispensing without prescription"; and 505(a)—the articles were new drugs within the meaning of the law, and no applications were filed pursuant to 505.

**PLEA:** Guilty by Seymour Blau to all counts except those alleging the adulteration of the tablets and not guilty by the corporation and Ludwig Spandau to all counts.

**DISPOSITION:** On 8-3-59, the case against the corporation and Ludwig Spandau came on for trial before the court without a jury. The trial was concluded on 8-5-59, and at that time the court found Ludwig Spandau guilty and the corporation not guilty. On 9-9-59, Ludwig Spandau was given a suspended sentence of 6 months imprisonment and placed on probation for 1 year, and Seymour Blau was fined \$200 and placed on probation for 1 day.

**6042. Meprobamate tablets.** (F.D.C. No. 42475. S. Nos. 35-394 P, 35-397 P.)

**INFORMATION FILED:** 10-9-59, E. Dist. Pa., against Jan Laboratories, Philadelphia, Pa., a partnership, Jerry Levin, a partner in the partnership, and Edward Lavin, a salesman for the partnership.

**ALLEGED VIOLATION:** The information alleged that, on 4-29-58, while a number of *meprobamate tablets* were being held for sale after shipment in interstate commerce, Jan Laboratories and Jerry Levin caused a number of the tablets to be repacked into a bottle and did sell and dispose of the bottle at Philadelphia, Pa., which acts of causing the repacking, sale, and disposal resulted in the drug being misbranded within the meaning of 502(a).



The information alleged also that all of the defendants, on 4-30-58, caused to be shipped from Philadelphia, Pa., to Pleasantville, N.J., a number of tablets which were in violation of 505(a), and which were misbranded under 502(a).  
 CHARGE: 502(a)—The label statement "For Investigational and Export Use Only" was false and misleading in that the article was not for investigational and export use only; and 505(a)—the article was a new drug which may not be introduced into interstate commerce, since an application filed pursuant to 505(b) was not effective with respect to such drug.

PLEA: Nolo contendere.

DISPOSITION: 3-22-60. Partnership—probation for 5 years; Levin—\$2,250 fine, 6 months jail sentence which was suspended, and probation for 5 years; Lavin—\$1,250 fine, 4 months jail sentence which was suspended, and probation for 5 years.

## DRUGS REQUIRING CERTIFICATE OR RELEASE, FOR WHICH NONE HAD BEEN ISSUED

### DRUGS FOR HUMAN USE

6043. Various drugs. (F.D.C. No. 41978. S. Nos. 31-201/2 P, 31-204/6 P.)

QUANTITY: 8,665 capsules of *Vi-Aquamin Therapeutic* in unlabeled ctns., 172 2-oz. btls. of *Pen-Vee suspension benzathine penicillin V*, 300 capsules of *chloramphenicol* in unlabeled btls., 143 boxes of *Chlorhidrate De Neohetramine*, and 2 unlabeled 500-tablet btls. of *Terramycin*, at Brooklyn, N.Y.

SHIPPED: On various dates during 1957 and 1958, from points outside the State of New York.

LABEL IN PART: (Btl.) "Pen Vee Suspension Benzathine Penicillin V Oral \* \* \* Each 5 cc contains 180 mg. (300,000 units)" and (box) "Chlorhidrate De Neohetramine \* \* \* 25 Mg."

RESULTS OF INVESTIGATION: The Pen-Vee penicillin V was analyzed and found to be penicillin having a potency of 273,600 units per 5 cc. The article had separated and had a lumpy consistency.

LIBELED: 8-14-59, E. Dist. N.Y.

CHARGE: *Vi-Aquamin Therapeutic capsules*, 502(b)—while held for sale, the label of the article failed to bear (1) the name and place of business of the manufacturer, packer, or distributor and (2) an accurate statement of the quantity of contents; 502(e)—its label failed to bear (1) the common or usual name of the drug and (2) the common or usual name of each active ingredient; and 502(f)(1)—the labeling of the article failed to bear adequate directions for use.

*Pen-Vee suspension benzathine penicillin V*, 501(c)—while held for sale, the strength of the article differed from, and its quality fell below, that which it purported and was represented to possess since the article contained less than 300,000 units of penicillin per 5 cubic centimeters and since it had separated and had a lumpy consistency; and 502(1)—the article contained penicillin, and was not from a batch with respect to which a certificate or release issued pursuant to 507 was effective.

*Chloramphenicol capsules*, 502(b)—while held for sale, the article failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor and (2) an accurate statement of the quantity of contents; 502(e)(1)—it failed to bear a label containing the common or



usual name of the drug; 502(f)(1)—its labeling failed to bear adequate directions for use; 502(f)(2)—its labeling failed to bear the warning relating to blood dyscrasias which may be associated with its use; 502(1)—it contained chloramphenicol, and it was not from a batch with respect to which a certificate or release had been issued pursuant to 507; and 503(b)(4)—it was a drug which was subject to the provisions of 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

*Chlorhidrate De Neohetramine*, 502(c)—while held for sale, the information required to appear on the label did not appear in such terms as to render it likely to be understood by the ordinary individual under customary conditions of purchase and use since such information was not printed in the English language; 502(e)(1)—it failed to bear a label containing the common or usual name of the drug; and 502(f)—its labeling failed to bear (1) adequate directions for use and (2) a warning that the user should not drive a car or operate machinery since the product may cause drowsiness.

*Terramycin*, 502(b)—while held for sale, the article failed to bear a label containing (1) the name and place of business of the manufacturer, packer or distributor and (2) an accurate statement of the quantity of contents; 502(e)(1)—it failed to bear a label containing the common or usual name of the drug; 502(f)(1)—its labeling failed to bear adequate directions for use; and 503(b)(4)—it was a drug which was subject to the provisions of Section 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

The libel alleged also that an article labeled Homicebrin was misbranded under the provisions of the law applicable to foods as reported in notices of judgment on foods.

DISPOSITION: 1-8-60. Default—destruction.

#### DRUG FOR VETERINARY USE

6044. Medicated feed. (F.D.C. No. 43195. S. Nos. 52-634 P.)

QUANTITY: 18 50-lb. bags at Mankato, Minn.

SHIPPED: 4-10-59, from Muscatine, Iowa, by Grain Processing Corp.

LABEL IN PART: (Tag) "From Grain Processing Corp. Muscatine, Iowa. Antibiotic Bacitracin Feed Supplement 10 Grams Bacitracin/Lb."

LIBELED: 6-22-59, Dist. Minn.

CHARGE: 502(1)—when shipped, the article contained manganese bacitracin, and it was not from a batch with respect to which a certificate or release had been issued in accordance with regulations.

DISPOSITION: 8-6-59. Default—destruction.

#### DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS\*

6045. Dur-Den-Col. (F.D.C. No. 43037. S. No. 6-248 P.)

QUANTITY: 15 cases, 12 btls. each, at Johnson City, Tenn.

SHIPPED: 3-5-59, from Norton, Va., by Southwest Pharmaceutical Corp., Inc.

LABEL IN PART: (Btl.) "Dur-Den" Col \* \* \* ingredients per fluid ounce—Tinc. Phytolacca 0.25 cc. Sodium Salicylate 0.43 gm. Potassium Iodide 43 mg. Methyl Salicylate \* \* \* 12 fluid ounces."

\*See also Nos. 6041, 6043.

RESULTS OF INVESTIGATION: Examination showed that each bottle contained 2.41 grams of sodium salicylate and 0.252 grams (252 milligrams) of potassium iodide per fluid ounce.

LIBELED: 5-29-59, E. Dist. Tenn.

CHARGE: 501(c)—when shipped, the strength of the article differed from that which it purported and was represented to possess; 502(a)—the label statement "ingredients per fluid ounce \* \* \* Sodium Salicylate 0.43 gm. Potassium Iodide 43 mg." was false and misleading; and 502(f)(2)—the labeling of the article failed to warn that the article should be kept out of the reach of children and that if pain persisted or redness was present in conditions affecting children under 12 years of age, one should consult a physician immediately.

DISPOSITION: 11-19-59. Default—destruction.

**6046. Dermo-G ointment.** (F.D.C. No. 41926. S. No. 7-242 P.)

QUANTITY: 9,108 cartoned ½-oz. metal tubes, and 5,031 cartoned 2-oz. metal tubes, at Manchester, N.H., in possession of Dermo-G, Inc.

SHIPPED: Prior to 3-20-58, from New York, N.Y.

LABEL IN PART: (Tube & ctn.) "Dermo-G \* \* \* Active Ingredients: Sodium Borate (borax) Precipitated sulphur together with a soothing penetrating base containing no poisonous or harmful ingredients."

ACCOMPANYING LABELING: Leaflets entitled "Dermo-G Relieves Many Skin Worries" and "Dermo-G The Amazing Skin Ointment"; window and store fliers; a number of empty cartons for use in packaging the article; and a number of pieces of stationery.

LIBELED: 7-14-58, Dist. N.H.

CHARGE: 502(a)—the labeling accompanying the article, while held for sale, contained false and misleading representations that the article was an adequate and effective treatment for eczema, acne, pimples, barber's itch, itchy scalp, sunburn, household burns, piles, hemorrhoids, poison ivy, poison oak, fever blisters, and psoriasis; and 502(f)(2)—the article was offered for piles and hemorrhoids, and its labeling failed to warn that the article should not be used in case of rectal bleeding, an indication of a serious condition, and the labeling of the article also failed to warn against use of the article in conditions such as sunburn, household burns, poison ivy, hemorrhoids, fever blisters, etc., in which conditions the presence of a high concentration of sulfur would aggravate rather than help the condition.

DISPOSITION: 11-17-59. Consent—claimed by Dermo-G, Inc., and relabeled.

**6047. Shai Skin-Trete.** (F.D.C. No. 42900. S. No. 33-804 P.)

QUANTITY: 49 cartoned 2-oz. btls. at Philadelphia, Pa., in possession of Rosal Laboratories, Ltd.

SHIPPED: During September or October 1958, from New York, N.Y., by Rosal Laboratories, Ltd.

LABEL IN PART: (Ctn. and btl.) "Shai Skin-Trete Lanolin Added \* \* \* Rosal Laboratories, Ltd., Philadelphia and New York."

ACCOMPANYING LABELING: Leaflets entitled "Shai by Rosal Laboratories, Ltd."

RESULTS OF INVESTIGATION: The leaflets were printed locally for the dealer.

LIBELED: 3-24-59, E. Dist. Pa.

CHARGE: 502(e) (2)—when shipped and while held for sale, the label of the article failed to bear the common or usual name of each active ingredient; and 502(f) (1)—the labeling of the article failed to bear adequate directions for use for the purposes and conditions for which it was intended, namely, acne, scalp irritation, excessive itching, bed sores, irritations of feet, fungus infections, eczema, all types of burns, radiation fallout injuries, and industrial dermatitis.

DISPOSITION: 10-19-59. Default—destruction.

6048. Stan Dispenstick and Stan Styk. (F.D.C. No. 42568. S. No. 7-582 P.)

QUANTITY: 120,000 lipstick-type dispensers at Fairfield, Conn., in possession of Stanley Research Corp.

SHIPPED: During the period of 1-1-58 through September 1958, from New York, N.Y., by Private Labels, Inc.

LABEL IN PART: "Stan Formulated [or "Stan Styk"] \* \* \* Active Ingredients: Hexachlorophene 1%, Pyriline Maleate 1.5%, Benzyl Alcohol, Calamine in Sterated Petrolatum Lanolin Base Wt. 90 Grains \* \* \* Distributed by Stanley Research Corporation, Bridgeport, Conn."

ACCOMPANYING LABELING: Leaflets entitled "The Easy Way to a Cleaner Better Looking Complexion!" and display cards entitled "Stan Dispenstick" and "Check Pimples! Stan Styk."

LIBELED: 12-19-58, Dist. Conn.

CHARGE: 502(a)—when shipped and while held for sale, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for acne, pimples, minor rashes, and all skin blemishes; and 502(f) (2)—the labeling failed to bear adequate warnings against unsafe methods and duration of administration or application, in such manner and form, as are necessary for the protection of users, since the article contained an antihistamine drug (pyrilamine maleate) and its labeling failed to warn that the article was not for prolonged use, should not be used in the eyes, or over large areas of the body, and that if swelling or pain persisted or increased, its use should be discontinued and a physician consulted.

DISPOSITION: 3-10-60. Default—destruction.

6049. Supra Vite Special Food Supplement and Supra Vite Vitamin E Perles. (F.D.C. No. 42425. S. Nos. 28-861/2 P.)

INFORMATION FILED: 5-18-59, N. Dist. Tex., against S. Evans Millican, Fort Worth, Tex.

ALLEGED VIOLATION: On 5-22-58, the defendant in the course of a sales talk to persons present, made oral representations holding out *Supra Vite Special Food Supplement* capsules and tablets and *Supra Vite Vitamin E Perles* capsules as a prevention and treatment for the diseases, symptoms, and conditions set forth below, which acts resulted in the articles being misbranded while held for sale.

LABEL IN PART: (Box) "SUPRA VITE Special Improved Highly Concentrated Food Supplement This package contains 122 multiple-vitamin capsules and 122 multiple-mineral tablets" and (btl.) "100 Capsules Supra Vite 50 mg. Vitamin E Perles."

CHARGE: 502(f) (1)—The labeling of the articles failed to bear adequate directions for use in the prevention and treatment of the diseases, symptoms, and



conditions for which they were intended, namely, (Special Food Supplement) anemia, allergy, diabetes, impotency, thrombosis, muscular dystrophy, alcoholism, sclerosis of the liver, nervousness, post-operative cancer conditions, and adverse reactions from antibiotics therapy; and, when used in conjunction with vitamin E therapy, phlebitis, heart trouble, nephritis, varicose veins, and chronic conditions of any sort, which are the diseases, symptoms, and conditions for which said drug was held out to the persons present at the aforesaid sales talk; and (Vitamin E Perles) heart trouble, impotency, nervousness, and chronic conditions of any sort; and, when used in conjunction with other vitamin and mineral therapy, phlebitis, varicose veins, nephritis, and diabetes, which are the diseases, symptoms, and conditions for which said drug was held out to the persons present at the aforesaid sales talk.

PLEA: Guilty.

DISPOSITION: 4-6-60. \$100 fine, six months jail sentence which was suspended, and probation for 1 year.

**6050. Various prescription drugs.** (F.D.C. No. 44215. S. Nos. 46-613/4 P, 46-616/8 P, 92-317 P.)

QUANTITY: 5 100-tablet btl. of *Obocell*, 7 100-tablet btl. of *Syndrox Methamphetamine Hydrochloride*, 3 12-tablet btl. of *penicillin G potassium* (200,000 Units), 1 12-tablet btl. of *penicillin G potassium* (50,000 Units), 5 individually cartoned tubes of *No. 66 ointment*, 1 50-tablet btl. of *Equanil*, 1 50-tablet btl. of *Dexamyl*, 1 50-tablet btl. of *Try-Phetamine Compound No. 3 Pink*, 1 12-tablet btl. of *penicillin G* (100,000 units), 3 25-troche btl. of *Ledercillin Troches*, 1 1-oz. tube of *Lederle Aureomycin ointment*, 2 1-oz. tubes of *Ledercillin procaine penicillin G ointment*, 1 100-tablet btl. of *Beltergal*, 1 ¼-lb. btl. of *chloroform*, 1 ¼-pint btl. *nux vomica NF* at *Fultondale, Ala.*, in possession of *Sam K. Mickwee, t/a Fultondale Sundry Store*.

SHIPPED: Prior to 12-18-59, from outside the State of Alabama.

LIBELED: 2-1-60, N. Dist. Ala.

CHARGE: 502(f) (1)—while held for sale, the labels of the articles failed to bear adequate directions for use, and the articles were not exempt from that requirement by regulations since the articles were prescription drugs in possession of a person who was not regularly and lawfully engaged in the distribution of prescription drugs, or regularly and lawfully engaged in dispensing prescription drugs.

DISPOSITION: 3-7-60. Default—destruction.

**6051. Kay-San ointment.** (F.D.C. No. 44164. S. Nos. 80-184/6 P.)

QUANTITY: 14 cases, 24 ¾-oz. jars each, and 24 cases, 12 1⅜-oz. jars each, at *Detroit, Mich.*

SHIPPED: Between 4-15-59 and 10-21-59, from *Wilkes-Barre, Pa.*, by *Stenton Laboratories, Inc.*

LABEL IN PART: (Ctn. and jar) "Kay-San \* \* \* Active Ingredients Mercury Salicylate ⅓ Gr. to Oz., Acid Salicylic, Resorcin, Coal Tar \* \* \* *Stenton Laboratories, Inc., Wilkes-Barre, Pa.*"

ACCOMPANYING LABELING: Leaflets in carton entitled "Pauling's Special" and "Kay-San" and sets of counter and display posters, consisting of three posters per set, reading in part "Stop That Itch with Kay-San."

**LIBELED:** 1-5-60, E. Dist. Mich.

**CHARGE:** 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for eczema, fungus infections, psoriasis, ringworm, and athletes foot; and 502(f) (2)—the labeling of the article failed to bear a warning that its use should be discontinued if undue or unusual irritation of the skin developed and that frequent or prolonged use or application to large areas of the body may cause serious mercury poisoning.

**DISPOSITION:** 4-8-60. Consent—destruction.

## DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARD

### DRUGS FOR HUMAN USE\*

**6052. Lobie #1 tablets.** (F.D.C. No. 43069. S. No. 25-122 P.)

**INDICTMENT RETURNED:** 9-14-59, S. Dist. Iowa, against Sentral Laboratories, Inc., Des Moines, Iowa, and James H. Roberts, president.

**ALLEGED VIOLATION:** On 11-25-57, the defendants gave to a firm engaged in the business of shipping drugs in interstate commerce, including *Lobie #1 tablets* supplied by the defendants, an invoice containing a guaranty that the Lobie #1 listed in the invoice was neither adulterated nor misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act.

On 11-25-57, the defendants sold, invoiced, and shipped a quantity of *Lobie #1 tablets*, which were adulterated, to the holder of the guaranty at Council Bluffs, Iowa.

**LABEL IN PART:** (Drum) "50,000 Lobie # 1 Each tablet contains: dl-Desoxyephedrine Hcl. 4 mg. Thyroid 1 gr. Atropine Sulfate 1/360 gr. Aloin ¼ gr."

**CHARGE:** 501(c)—the strength of the article differed from that which it purported and was represented to possess, namely, 4 milligrams of dl-desoxyephedrine hydrochloride in each tablet, since each table of the article contained more than 4 milligrams of dl-desoxyephedrine hydrochloride.

**PLEA:** Guilty.

**DISPOSITION:** 12-3-59. Fines were assessed in the amount of \$2,500 against the corporation and \$1,000 against the individual, plus costs.

**6053. Procaine hydrochloride injection.** (F.D.C. No. 43327. S. Nos. 48-543 P, 48-822 P.)

**QUANTITY:** 13,045 vials and 840 pkgs., 12 vials each, at San Francisco, Calif., in possession of Allied Biochemical Laboratories.

**SHIPPED:** Procaine hydrochloride was shipped on 1-29-59, from St. Louis, Mo.

**LABEL IN PART:** (Vial) "30 cc. Sterile Procaine Hydrochloride Injection USP 1% [or "2%"]."

**RESULTS OF INVESTIGATION:** The *procaine hydrochloride injection* was manufactured by the dealer from the procaine hydrochloride which was shipped as described above. Examination of the article showed that the pH (acidity) of procaine hydrochloride was less than 3.3, whereas the United States Pharmacopeia requires that the pH of *procaine hydrochloride injection* be between 3.3 and 5.5.

\*See also Nos. 6041, 6043, 6045.

**LIBELED:** 8-4-59, N. Dist. Calif.

**CHARGE:** 501(b)—while held for sale, the quality of the article fell below the standard for *procaine hydrochloride injection* set forth in the United States Pharmacopeia; and 502(a)—the label statement "Procaine Hydrochloride Injection USP" was false and misleading.

**DISPOSITION:** 10-5-59. Default—destruction.

**6054. Del-Caps timed disintegration capsules.** (F.D.C. No. 42794. S. No. 45-496 P.)

**QUANTITY:** 8 1,000-capsule btls. at Tulia, Tex.

**SHIPPED:** 9-17-58, from Rensselaer, N.Y., by Delmar Pharmacal Corp.

**LABEL IN PART:** "Del-Caps 15 Timed Disintegration Capsule \* \* \* Each Capsule Contains Dextro Amphetamine Sulfate 15 mg. \* \* \* in a special base that provides for the disintegration of the contents throughout a period of 6-10 hours. \* \* \* 3565 Manufactured by Delmar Pharmacal Corp. 333 Columbia Street, Rensselaer, New York."

**RESULTS OF INVESTIGATION:** Analysis showed that each capsule contained 15 mg. of dextro-amphetamine sulfate, 77 percent of which was released in two hours.

**LIBELED:** 2-2-59, N. Dis. Tex.; libel amended 5-12-59.

**CHARGE:** 501(c)—when shipped, the quality of the article differed from that which it purported and was represented to possess since it failed to disintegrate at a uniform rate over a 6-10 hour period; and 502(a)—the label statement "Each capsule contains Dextro Amphetamine Sulfate 15 mg. \* \* \* in a special base that provides for the disintegration of the contents throughout a period of 6-10 hours" was false and misleading.

**DISPOSITION:** 1-15-60. Default—destruction.

#### DRUGS FOR VETERINARY USE

**6055. Clotin.** (F.D.C. No. 42878. S. No. 53-904 P.)

**QUANTITY:** 10 cases, 12 tins each, at Springdale, Ark.

**SHIPPED:** 10-29-58, from Omaha, Nebr., by Gland-O-Lac Co.

**LABEL IN PART:** (Tin) "Gland-O-Lac 2 Lb. 6 oz. (1.25 Kilos) CLOTIN A stabilized soluble Vitamin K effective without the addition of bile salts, for the prevention of Vitamin K deficiency in poultry and for the correction of hemorrhagic disease due to such deficiency. Active Ingredient: Menadione Sodium Bisulfite, U.S.P. Each level teaspoonful (3 grams) contains 8.25 milligrams equal to 0.275%. Gland-O-Lac Company, Omaha, Nebr."

**RESULTS OF INVESTIGATION:** Examination showed that the article contained substantially less than the declared amounts of menadione sodium bisulfite.

**LIBELED:** 3-9-59, W. Dist. Ark.

**CHARGE:** 501(c)—when shipped, the strength of the article differed from that which it purported and was represented to possess.

**DISPOSITION:** 8-4-59. Default—destruction.

**6056. Medicated poultry feed.** (F.D.C. No. 43058. S. Nos. 7-592 P, 7-887 P, 7-964 P.)

**INFORMATION FILED:** 12-4-59, Dist. Mass., against H. K. Webster Co., a corporation, Lawrence, Mass., and Walter N. Webster, vice president and treasurer of the corporation.



SHIPPED: Between 7-7-58 and 8-26-58, from Massachusetts and Vermont to New Hampshire and Maine.

LABEL IN PART: (Tag attached to bags) "CHICK STARTER MEDICATED" and "BLUE SEAL ALL-MASH GROW and LAY MEDICATED"; (invoice) "Growing Mash-Spec. Mix."

CHARGE: 501(d)(2)—products containing sulfaquinoxaline and no glycarbylamide had been substituted for products containing glycarbylamide and no sulfaquinoxaline; 502(a)—the statement on the labels of the *Chick Starter* and the *Blue Seal Mash*, namely, "Glycarbylamide \* \* \* 0.002%" was false and misleading since the products did not contain glycarbylamide; and 502(e)(2)—the labels of all products failed to bear the common or usual name of the active ingredient sulfaquinoxaline contained in the products.

PLEA: Nolo contendere.

DISPOSITION: 2-29-60. Fine of \$300 against each defendant.

### DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS\*

6057. Various vitamin and mineral tablets. (F.D.C. No. 43612. S. Nos. 41-963/76 P.)

QUANTITY: 2 bulk ctns., each containing 15,000 capsules, and 9 cases, each containing 12 100-capsule btl., of vitamin A 25,000 U.S.P. Units; 2 bulk ctns., containing a total of about 21,000 capsules, and 11 cases, each containing (Howco brand) 12 100-capsule btl., and (Apothecary brand) 5 cases, each containing 24 100-capsule btl. of vitamin A 50,000 U.S.P. Units; 1 bulk ctn., containing about 22,000 capsules, 3 cases, each containing 24 150-capsule btl., and 150 unlabeled 150-capsule btl. of multiple vitamins; 1 bulk ctn., containing about 4,000 capsules, and 9 100-capsule btl. of Improved Vitamin Formula with Minerals and B<sub>12</sub>; 1 bulk ctn. containing about 40,000 tablets of vitamin B<sub>12</sub> 5 mcg.; 1 bulk ctn., containing about 8,000 tablets, and 25 cases, each containing 12 100-tablet btl., of vitamin B<sub>12</sub> 10 mcg.; 1 bulk ctn., containing about 30,000 tablets, and 7 cases, each containing 12 100-tablet btl. of vitamin B<sub>1</sub> (thiamine) 25 mg.; 1 bulk ctn., containing about 30,000 tablets, and 13 cases, each containing 12 100-tablet btl., of vitamin B<sub>1</sub> (thiamine) 50 mg.; 1 bulk ctn., containing about 100,000 tablets, and 13 cases, each containing 12 100-tablet btl., of vitamin C (ascorbic acid) 50 mg.; 1 bulk ctn., containing about 90,000 tablets, and 60 250-tablet btl. of vitamin C (ascorbic acid) 250 mg.; 1 bulk ctn., containing about 281,000 tablets, 1 bulk ctn., containing about 117,000 tablets, 316 100-tablet btl. (Howco brand), and 7 cases, each containing 24 100-tablet btl. (Apothecary brand), of vitamin C (ascorbic acid) 100 mg., and 1 ctn. containing about 10,000 tablets and 13 cases, each containing 12 100-tablet btl. of vitamin B<sub>12</sub> 5 mcg., at Seattle, Wash., in possession of Howe Products, Inc.

SHIPPED: Between 1-29-59 and 6-26-59, from Detroit, Mich.; San Francisco, Calif.; and Brooklyn, N.Y.

LABEL IN PART: (Btl.) "Howco Vitamin A \* \* \* 25,000 [or "50,000"] U.S.P. Units \* \* \* Distributor Howe & Co. Seattle"; "Apothecary Brand Multiple Vitamins \* \* \* As a dietary supplement for children and adults"; "Apothecary Brand Improved Therapeutic Vitamin Formula with Minerals and B<sub>12</sub> \* \* \* Distributed by Apothecary Products, Co., Seattle, Wash."; "Howco

\*See also Nos. 6042, 6045, 6046, 6048, 6051, 6053, 6054, 6056.

Vitamin B<sub>12</sub> Activity (from cobalemin concentrate NF) 10 mcg."; "Howco Vitamin B-1 \* \* \* 25 mg. [or "50 mg."]; "Howco Vitamin C \* \* \* 50 mg."; "Howco Vitamin C Ascorbic Acid USP 250 mg. [or "100 mg."]."

ACCOMPANYING LABELING: Display cards entitled "Quality Vitamins," which hold one bottle and are used to display the "Apothecary Brand," and leaflets entitled "Vitamin Data" which accompany all the articles.

RESULTS OF INVESTIGATION: The articles in the bottles were repacked and relabeled by the dealer from bulk stock shipped as described above.

The display cards and the leaflets were printed locally at the dealer's request.

LIBELED: 11-3-59, W. Dist. Wash.

CHARGE: 502(a)—while held for sale, the labeling which accompanied the articles contained false and misleading representations as follows:

*Vitamin A 25,000 and 50,000 U.S.P. Units* (bulk and repacked), the statements "Common Name, Anti-infective; Anti-ophthalmic \* \* \* Function, Aids Growth & Vitality—Necessary for Reproduction \* Helps Prevent Infection, \* \* \* Deficiency Symptoms, Low resistance to Infection—Retarded Growth—Loss of Vigor—Night Blindness" were false and misleading since the article was not an adequate and effective treatment for, or preventive of, such conditions, since these conditions, namely, infections, low resistance to infections, ophthalmic disorders, retarded growth, low vitality, sterility, loss of vigor, and night blindness, implied or suggested by the labeling are rarely, if ever caused by a deficiency of vitamin A, and then only after a prolonged deficiency of vitamin A in the diet; and the statement "Natural Sources, Green vegetables, Tomatoes, Eggs, Butter" was false and misleading since vitamin A is abundantly available in many articles of food which comprise the normal diet and not only in those foods listed in the labeling.

*Multiple vitamins* (bulk and repacked), the statements "Function, One Capsule daily supplies a daily ration of all essential vitamins. Nutritional Supplement General resistance to colds and infections. Deficiency Symptoms Lack of resistance to colds and infections. Poor appetite and digestion" were false and misleading since the article was not an adequate and effective treatment for, or preventive of, lack of resistance to colds and infections, and the conditions, namely, poor appetite and digestion, are rarely, if ever, caused by a deficiency of the vitamins in the article and then only after a prolonged deficiency of such vitamins in the diet; such deficiencies being very rare in this country, since the vitamins listed on the label of the article are abundantly available in the many articles of food which comprise the normal diet.

*Improved Therapeutic Vitamin Formula* (bulk and repacked), the statements "Function, Aids people with high vitamin requirements. Correction of known vitamin and mineral deficiencies. Deficiency Symptoms, Lack of general good health and energy—colds and infections, sluggish skin" were false and misleading since the article was not an adequate and effective treatment for colds and infections; colds and infections are not symptoms of vitamin deficiencies; and the conditions, lack of general good health, and energy, listed for the article and the vitamins contained therein, are rarely, if ever, caused by a deficiency of these vitamins and minerals and then only after a prolonged deficiency of such vitamins and minerals in the diet; such deficiencies being very rare in this country since the vitamins and minerals contained in the article, as listed on the label, are abundantly available in the many articles



of food which comprise the normal diet and not only in those listed in the labeling.

*Vitamin B<sub>12</sub>, 5 mcg. and 10 mcg.* (bulk and repacked), the statements "Common Name—Anti-pernicious-anemia principle. Function, Helps prevent certain anemias, promotes growth. Deficiency Symptoms, Certain anemias, retarded growth in children Natural Source Liver (Beef)" were false and misleading since anemia is not a symptom of dietary deficiency of vitamin B<sub>12</sub>; the article is not an adequate and effective treatment for pernicious anemia or any other anemia, vitamin B<sub>12</sub> is abundantly available in the many articles of food which make up the normal diet, and not only in the one listed in the labeling of the article; and since the condition, retarded growth, listed for the article, is rarely caused by a deficiency of vitamin B<sub>12</sub>.

*Vitamin B<sub>1</sub> (thiamine) 25 mg. and 50 mg.* (bulk and repacked), the statements "Common Name—Anti-neuritic; Anti-beriberi. Function, Aids appetite and digestion. Helps some form of neuritis. Stimulates body activity, Deficiency Symptoms, Loss of appetite—fatigue—neuritis—depression. Natural Source, Yeast, wheat germ, milk" were false and misleading since vitamin B<sub>1</sub> is abundantly available in the many articles of food which comprise the normal diet and not only in those listed in the labeling of the article; and since the listed conditions, neuritis, poor appetite and digestion, loss of appetite, fatigue, depression, are rarely caused by a deficiency of vitamin B<sub>1</sub> and then only after a prolonged deficiency of vitamin B<sub>1</sub> in the diet; and the article is not a stimulant to body activity except in severe cases of beriberi which is an extremely rare condition in this country.

*Vitamin C (ascorbic acid)* (bulk and repacked), the statements "Function, Assists in proper formation of bones and teeth—prevents scurvy. Deficiency Symptoms, Scurvy—tooth decay—hemorrhage—muscular weakness. Natural Source, Lemons, Oranges, Tomatoes, Grapefruit" were false and misleading since vitamin C is abundantly available in other articles of food which comprise the normal diet and not only in those listed in the labeling of the article; and since the listed conditions, tooth decay, hemorrhage, and muscular weakness are rarely caused by a deficiency of vitamin C and then only after a prolonged deficiency of vitamin C in the diet.

DISPOSITION: 11-23-59. Consent—claimed by Howe Products, Inc., and relabeled.

6058. **Silhouettes capsules.** (F.D.C. No. 43580. S. No. 75-206 P.)

QUALITY: 1 bulk drum containing about 7,000 capsules and 22 ctns., each containing 6 14-capsule boxes, at Chicago, Ill., in possession of N.D.L., Inc.

SHIPPED: 9-12-59, from Long Island City, N.Y.

LABEL IN PART: (Bulk drum) "Timed Disintegration Capsules Phenyl Propanolamine Hydrochloride 75 mgm. Each capsule contains 75 mgm. Phenyl Propanolamine Hydrochloride in a special timed disintegration base that provides for prolonged therapeutic effect for about 6 to 10 hours" and (box) "Silhouettes \* \* \* An Effective Aid to Appetite Control Active Ingredient: 75 Mgs. Phenyl Propanolamine Hydrochloride."

RESULTS OF INVESTIGATION: The tablets in the boxes were repacked and relabeled from tablets in the bulk drum shipped as described above.

LIBELED: 10-7-59, N. Dist. Ill.

CHARGE: 502(a)—while held for sale, the labeling of the article and the name "Silhouettes" contained false and misleading representations that the article



was adequate and effective in controlling the appetite and causing one to lose weight.

DISPOSITION: 11-3-59. Default—destruction.

**6059. Energol Germ Oil Concentrate.** (F.D.C. No. 43317. S. No. 52-100 P.)

QUANTITY: 5 8-oz. btls. and 50 16-oz. btls. at Minneapolis, Minn.

SHIPPED: Between 12-18-58 and 5-4-59, from York, Pa., by York Barbell Co.

LABEL IN PART: "Hoffman's Energol Germ Oil Concentrate \* \* \* Mfg. by Bob Hoffman, York Barbell Co. York, Pa. \* \* \* a blend of Wheat Germ Oil, Soy Oil, and Rice Germ Oil."

ACCOMPANYING LABELING: Leaflets entitled "Energol Hoffman's Germ Oil Concentrate."

LIBELED: 7-28-59, Dist. Minn.

CHARGE: 502(a)—when shipped and while held for sale, the labeling of the article contained false and misleading representations and suggestions that the article was an adequate and effective treatment and preventative for arteriosclerosis, coronary thrombosis, coronary occlusion, stroke, high blood pressure, gangrenous ulcers, eczema, Bergers disease, gallstones, cell production, cirrhosis of the liver, gangrene, sore tongues, nervousness, anemia, epilepsy, difficulty in walking, pathological changes in the liver, thyroid, and sex glands, inflammation of the intestines, extreme fatigue, oil secretion in eyelashes, bloodshot lip, swollen under eyes, quarrelsome, mentally sluggish, numbness, low blood pressure, shortage of breath, severe headaches, gas pains, flatulence, insufficient gastric juices, lack of hydrochloric acid, shingles, arthritis, alcoholism, underactive pituitary glands, waddling gait, unusual sensitivity to pain, changes in the bone marrow, changes in the nodes, lack of fertility, changes in the nerves, stunted growth, middle age spread, premature aging, overweight, stimulation of bile, heart attacks, sore mouths, mental depression, insomnia, dizziness, irritability, tremors, nervous tics, blackouts, cataracts, tongue abnormalities, watery eyes, inefficient, depressed, sensitivity to noise, low basic metabolism, enlarged heart, vomiting, muscular contraction of the stomach, headache, diarrhea, tri facial neuralgia, sciatica, rheumatism, irregular menstruation, lack of strength, skin lesions, emaciation, sexual disturbances, coco pigmentation, changes in the brain cells, lagging secondary sex characteristics, swelling of the feet and ankles, inactive ovaries, muscular and joint stiffness, diabetes, gangrenous ulcers, sore lips, extreme weakness, nausea, convulsions, paralysis, tension, duodenal ulcers, adrenal deficiency, aching feet, neuritis, bloodshot eyes, weak eyes, burning eyes, forgetfulness, constipation, heart palpitation, pain in muscles, low energy production, sick stomach, heart abnormalities, lumbago, premature menopause, lack of coordination, eye infections, ear infections, changes in the lymph, changes in the spleen, too rapid growth, edema, muscular dystrophy, strains, atrophy of the testicles, and cardiac conditions.

The article was alleged also to be misbranded under the provisions of the law applicable to food as reported in notices of judgment on foods.

DISPOSITION: 11-4-59. Consent—claimed by the Pavo Co., Inc., Minneapolis, Minn., and relabeled.

**6060. Iodine preparation.** (F.D.C. No. 43937. S. No. 77-694 P.)

QUANTITY: 2 5-gal. containers and 1-oz. btl. at Cleveland, Ohio, in possession of Inorganic Bioelements, Inc.

**SHIPPED:** 3-6-59 and 8-27-59, from Oak Ridge, Tenn., by Martin Anderson Co.

**LABEL IN PART:** (5-gal. containers) "Amidal An Iodine Preparation Active Ingredients: Edible Proteins consisting of Gelatin, Extract of Algae and Pepsin, and 5% of Iodine in the form of Sodium Compounds, including Sodium Iodide, Sodium Iodate, and Sodium Hypiodite. Indicated as a source of iodine for nutritional purposes and for the prevention of goiter, in animals. Directions: \* \* \*  $\frac{1}{2}$  Fluid Gallon Distributed By Inorganic Bioelements, Inc. \* \* \* Cleveland 10, Ohio" and (btl.) "Amio 5% Nutritional Iodine Preparation for Human Use \* \* \* Inorganic Bioelements, Inc., Cleveland 10, Ohio Distributor."

**ACCOMPANYING LABELING:** Literature and leaflets entitled "The Importance of Iodine in the Nutrition of Farm Animals," and "The Importance of Iodine in Nutrition"; and a number of loose "Amio" and "Amidal" labels.

**RESULTS OF INVESTIGATION:** Analysis showed that the article (5-gal. containers) contained 1.42 percent free iodine and a total iodine content of 5.20 percent, and (bottle) 0.68 percent free iodine and a total iodine content of 5.82 percent. The bottle was repacked and labeled by the dealer from the 5 gal. containers shipped as described above.

**LIBELED:** 12-4-59, N. Dist. Ohio.

**CHARGE:** 502(a)—when shipped and while held for sale, the labeling of the article contained false and misleading representations that the article (bottle) was adequate and effective for the prophylaxis and prevention of goiter; and for the treatment of moping, inattentiveness; subnormal body temperature; cold hands and feet; accumulation of excess flabby flesh; dry, fallow skin; dry, falling hair; greying hair; melancholic outlook; osteoarthritis; hay fever; arthritis; and that the article would stimulate the production of the glands, notably the parathyroid and the adrenals; result in a greater production of cortisone; develop better hair and skin, and normal brain in children; activate enzymes and vitamins; and develop better metabolism and better health; and (5-gal. container) for the prevention of goiter in animals, including dairy cows, beef animals, horses, dairy goats, sheep, swine, chickens, turkeys, dogs, and fur-bearing animals; for hairlessness in pigs; rough coat; unthriftiness; stiff joints; lameness; poor viability; interference with reproductive processes; infestations of worms or other intestinal parasites; and would activate the thyroid, the parathyroid, and other glands and their hormones; stimulate the parasympathetic nerves that govern the body level of calcium and phosphorus; produce good bones and teeth, eggshell, and milk solids; promote growth of hair and feathers; improve quality of skin and eyes; better the quality of milk by increasing the iodine content of the milk; and that the article would develop a synergistic effect with trace amounts of manganese, zinc, magnesium, and cobalt in the rations.

The libel also charged that the article was misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

**DISPOSITION:** 1-18-60. Default—destruction.

**6061. Bipanzyne tablets.** (F.D.C. No. 42588. S. No. 73-625 P.)

**QUANTITY:** 43,000 tablets in btls. of 5,000 (2 btls.), 1,000 (25 btls.), 500 (10 btls.), and 100 (30 btls.) tablets, at Birmingham, Ala., in possession of Veltex Co.

**SHIPPED:** The tablets were shipped in bulk on 5-5-59, from Philadelphia, Pa.



LABEL IN PART: (Btl.) "Code 917X \* \* \* Bipanzyme \* \* \* The Veltex Company Distributors—Birmingham, Alabama \* \* \* Each Tablet Contains: Pancreatin USP 300 Mg. Pepsin, NF 250 Mg. Bile Salts 150 Mg."

ACCOMPANYING LABELING: Printed sheets on Veltex Co. letterhead entitled "Diabetes Studies From New Angle" by William L. Lawrence.

RESULTS OF INVESTIGATION: The article in the bottles was repacked by Veltex Co. from bulk stock which had been shipped as described above.

LIBELED: 10-12-59, N. Dist. Ala.

CHARGE: 502(a)—while held for sale, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for diabetes, indigestion, heartburn, belching, flatulence, nausea, psoriasis, and specific digestive deficiencies.

DISPOSITION: 11-12-59. Default—destruction.

**6062. Canker-Eze.** (F.D.C. No. 43424. S. No. 49-085 P.)

QUANTITY: 13 envelopes, each containing one placard and 12 3-gram tubes of *Canker-Eze*, at South San Francisco, Calif.

SHIPPED: 7-28-59, from Seattle, Wash., by Canker-Eze Co.

LABEL IN PART: (Envelope) "For relief of canker sores Canker-Eze—\* \* \* The Canker-Eze Co., Seattle, Wash.—Weight 5 Gm."; (tube) "The Canker-Eze Company, \* \* \* Wt. 3 Gm. \* \* \* contains magnesium trisilicate, aluminum hydrate, sodium acid carbonate, benzocaine"; and (placard) "For relief of canker."

LIBELED: 8-17-59, N. Dist. Calif.

CHARGE: 502(a)—when shipped, the name and the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for canker sores.

DISPOSITION: 10-5-59. Default—destruction.

**6063. Davis Union remedy.** (F.D.C. No. 43551. S. No. 73-635 P.)

QUANTITY: 40 12-oz. cartoned btls. at Montgomery, Ala.

SHIPPED: 7-23-59, from Pensacola, Fla., by Johns Distributing Co.

LABEL IN PART: (Ctn.) "Davis Union Remedy \* \* \* This medicine contains, buchu leaves, mandrake root, culver root, rhubarb root, ginger root, gentian root, sarsaparilla root, juniper berries, wahoo bark, prickly ash bark, epsom salts and soluble extracts of senna leaves, bitterapple, and caramel coloring, aromatic cascara, salicylic acid, and 1.08% alcohol."

ACCOMPANYING LABELING: (Circular in ctn.) "Davis Union Remedy \* \* \* Many People have found relief."

LIBELED: 9-30-59, M. Dist. Ala.

CHARGE: 502(a)—when shipped, the labeling contained false and misleading representations that the article was an adequate and effective treatment for diseases of the liver, kidneys, blood, and stomach; and for rheumatism, diabetes, headaches, and many other daily complaints.

DISPOSITION: 11-4-59. Default—destruction.

**6064. Zest capsules.** (F.D.C. No. 43616. S. Nos. 53-638 P, 53-659 P.)

QUANTITY: 30,000 capsules in bulk and 200 sets, each set containing 1 30-capsule plastic container and 1 7-capsule trial btl., at Los Angeles, Calif., in possession of Royalin Co., Inc.



SHIPPED: 9-4-59 and 10-16-59, from Philadelphia, Pa.

LABEL IN PART: (30-capsule size) "ZEST FORMULA 30 Time Disintegration Capsules 'Pep' in Minutes! Lasts for Hours! \* \* \* Royalin Company, Inc. Los Angeles 48, Calif. Each Capsule contains: Trimethylxanthine (caffeine alkaloid), 165 mgm; Thiamin Chloride (Vit. B-1), 5 mgm, \* \* \* Riboflavin (Vit. B-2) 1.2 mgm, \* \* \* Niacin, 10 mgm \* \* \* Pyridoxine HCl (Vit. B-6) 0.5 mgm; Cobalamin Conc.—(Vit. B-12), 1 mcg; Dextrose powdered \* \* \* Adult Dose: 1 or 2 capsules in the morning"; and (trial-size) "Zest Formula Trial Sample. Each Capsule Contains."

ACCOMPANYING LABELING: Pamphlets entitled "New Laboratory Miracle Zest."

RESULTS OF INVESTIGATION: The article in the plastic containers and the trial bottles was repackaged and labeled by the dealer from bulk stock shipped as described above, and the pamphlets were obtained locally by the dealer.

LIBELED: 10-28-59, S. Dist. Calif.

CHARGE: 502(a)—while held for sale, the labeling of the article contained false and misleading representations that the article was capable of giving anyone a "lift" in minutes; was capable of giving anyone a "lift" that lasts for hours; was especially effective for professional people in counteracting temporary mental and physical fatigue that may affect their business judgment and efficiency; would correct in homemakers, weariness and depression resulting from strenuous household chores; would effectively fight fatigue in laborers; would make oldsters feel younger; would in minutes give a quick charge of pep to athletes; would keep office workers wide awake and alert all day; was a revolutionary new "pep" pill for men and women that gives an immediate "lift" and wide-awake alertness to all persons whose energy and enthusiasm had been drained due to overwork, nervous strain, or emotional distress; contained trimethylxanthine (caffeine), a new ingredient, and was not an ordinary vitamin preparation.

DISPOSITION: 12-30-59. Default—destruction.

6065. Testone Wheat Germ Oil capsules. (F.D.C. No. 35581. S. Nos. 34-888 L, 43-776 L, 45-465 L, 54-673/5 L, 57-384 L.)

INFORMATION FILED: 10-7-54, S. Dist. N.Y., against Morris Silfan, t/a Canal Medical Products and New York Medical Products, Seward Laboratories, Inc., and Leo Savitch, president of the corporation, New York, N.Y.

SHIPPED: Between 5-20-53 and 7-16-53, from New York, N.Y., to St. Louis, Mo. (count 1), Jamaica Plain, Mass. (count 2), Baltimore, Md. (count 3), North Sacramento, Calif. (count 4), and Flint, Mich. (count 5).

LABEL IN PART: (Front panel) "MINIMCAPSULES Testone Wheat Germ Oil CAPSULES HORMONES As found in wheat. Nine capsules have activity equal to: Testosterone—6.6 mcg. Estrone—0.5 mcg. Survival Factor—Vitamin E—3.4 mgs. Need for hormones and Vitamin E in human nutrition not established. Units of measurement for wheat germ oil not established. Dist. by NEW YORK MEDICAL PRODUCTS 246 Fifth Avenue New York 1, N.Y."; and (right side panel) "Dosage: 3 capsules at each meal—the oil of 1½ pounds of fresh whole wheat daily."

ACCOMPANYING LABELING: Leaflets entitled "Men Past 40 if You have any of These Symptoms," "Want Proof of Testone's Effectiveness?," and an order blank headed "Don't Delay! \* \* \* Rush Your Testone Order Today."

**CHARGE:** 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article contained hormonal activity equivalent to therapeutically significant amounts of testosterone and estrone and that the article was an adequate and effective treatment for male hormone deficiency, loss of sex urge, sleeplessness, irritability, lack of vigor, nervousness, loss of muscle power, loss of pep, tiredness and premature old age, and that the article was effective to restore man to a life of vigor, vitality and sex enjoyment.

**PLEA:** Guilty by Silfan to counts 1, 2, 4 and 5; by Savitch to count 1; and by the corporation to counts 1, 2 and 3.

**DISPOSITION:** 3-28-60. Silfan—\$1,000 fine of which \$750 was remitted; 90 days in jail which was suspended; and probation for 1 year. Savitch—\$500 fine; 90 days in jail which was suspended; and probation for 1 year. Corporation—\$3 fine which was remitted.

**6066. Kelp tablets.** (F.D.C. No. 43118. S. No. 50-139 P.)

**QUANTITY:** 15 drums, each containing 64 lbs. in tablet form, 62 1,000-tablet cans, and 7 500-tablet cans, at Kingsport, Tenn., in possession of Thomas D. Pruitt.

**SHIPPED:** 12-24-58, from Kalamazoo, Mich.

**LABEL IN PART:** (Drum) "Each tablet contains: Pacific Kelp 5 gr." and (can) "5 grain tablets \* \* \* Pruitt's Pure Pacific Sea Kelp \* \* \* A Pure Natural Food to be used as a supplement to the regular diet, as nutrition only \* \* \* Packed and Distributed by T. D. Pruitt, \* \* \* Kingsport, Tennessee \* \* \* Average usage: 6 tablets three times daily, 18 tablets (90 grains) supplements the regular diet."

**ACCOMPANYING LABELING:** Leaflets entitled "Are You Starving" and "Food and Your Body."

**RESULTS OF INVESTIGATION:** The tablets in the cans were repacked and labeled by the dealer from the tablets in the drums shipped as described above.

The leaflets were furnished to customers by the dealer for promotional purposes.

**LIBELED:** 4-21-59, E. Dist. Tenn.

**CHARGE:** 502(a)—while held for sale, the labeling of the article contained false and misleading representations that the article, when used according to directions, was an adequate and effective treatment for producing and maintaining a normal and vigorous health, clear complexion, happier life, endurance, will power, vigor and stamina; that the article coagulated blood in wounds; prevented tuberculosis and rickets; was essential in digestion; purified body tissues; prevented excessive weight; kept joints supple; would distribute hormones in the body; was necessary for iron transfer from the food to the blood and for iron assimilation; aided in tissue respiration; was essential to every gland and for proper heart function; ejected and counteracted poisons; gave vitality and longer life; helped prevent "tired feeling," cold hands and feet, slow thinking, premature gray hair; was needed to carry oxygen to the blood; gave pep and strength; was required for firm tissues, bones, glands, and nerves; stimulated memory; prevented irritation and worry; aided production of enzymes; hardened bones and teeth; was an aid to body relaxation and good disposition; created body beauty; was essential for body activity; built brain and nerves; supplied recuperative



powers; flushed the kidneys; helped to prevent constipation; maintained normal heart beat; alkalized the blood; aided gland secretions; neutralized body acidity; prevented continual sense of hunger, sinus and catarrhal conditions; aided in preventing hardening of the arteries and cataract of the eyes; was essential for clear skin and glossy hair; cleansed and purified the blood; and prevented infection; stimulated liver and gall bladder secretions.

The libel alleged also that the article was misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 3-1-60. Consent—claimed by Thomas D. Pruitt and relabeled.

6067. 7/Eleven Health tablets. (F.D.C. No. 42823. S. No. 36-125 P.)

QUANTITY: 2 metal containers containing about 28,000 tablets at Philadelphia, Pa., in possession of Service Industries.

SHIPPED: 1-15-59, from San Pedro, Calif.

LABEL IN PART: (Metal container) "20,000 Brewers Yeast Alfalfa & Kelp (Special) Tablets"; (bottle label) "7/Eleven Mineral, Vitamin and Protein Health Tablets Each tablet 8.5 Grain Net Weight \* \* \* Vitamin Components \* \* \* Mgs. Per Tablet Riboflavin 0.0096 Niacin \* \* \* 0.1538 Chloride 1.1100 Carotene \* \* \* 0.0040 Pantothenic Acid \* \* \* 0.0755 Thiamine \* \* \* 0.0232 Pyridoxine \* \* \* 0.0090 Betaine \* \* \* 0.2176 Biotin \* \* \* 0.0002 Inositol 0.9060 Minodione \* \* \* 0.0024 Alpha Tocopherol \* \* \* 0.0532 Xanthophylls \* \* \* 0.0480 Choline \* \* \* 1.1100 \* \* \* Total Vitamin Components \* \* \* 3.7225 Protein (Amino Acids) Components \* \* \* Mgs. Per Tablet Arginine 10.747 Cystine \* \* \* 2.835 Histidine 5.478 Isoleucine 11.884 Lysine 14.914 Leucine 15.200 Methionine 4.686 Phenylalanine 8.732 Threonine 10.280 Tyrosine 9.092 Tryptophane 2.718 Valine 9.328 Glutamic Acid 20.240 Glycine 13.866 \* \* \* Total Protein \* \* \* Components in each 7/Eleven Tablet 140.00 Mineral Components \* \* \* Total Per Tablet Calcium \* \* \* 4.94 Phosphorus \* \* \* 3.58 Iron \* \* \* 0.365 Potassium \* \* \* 7.04 Magnesium \* \* \* 1.93 Manganese \* \* \* 0.94 Iodine \* \* \* 0.37 Sodium \* \* \* 5.80 Chloride \* \* \* 22.12 Sulphur \* \* \* 2.40 \* \* \* Total Mineral Components \* \* \* 49.485 Total U.S.P. Units of all three components for Dietary Supplement—64.175 Directions \* \* \* A Product of Service Industries \* \* \* Philadelphia 34, Pa."

ACCOMPANYING LABELING: Pamphlets entitled "7/Eleven Multiple Mineral, Vitamin and Protein Tablets" and a number of loose bottle labels.

RESULTS OF INVESTIGATION: The tablets in the metal containers were to be packed into bottles labeled as described above.

The bottle labels and the pamphlets were prepared and printed by the dealer for use in promoting sales of the tablets.

LIBELED: 2-11-59, E. Dist. Pa.

CHARGE: 502(a)—while held for sale, the labeling of the article, namely, the above-mentioned bottle labels and pamphlets, contained false and misleading representations that the article was an adequate and effective treatment in preventing and treating all disease and infections, including hardening of the arteries, arthritis, instability of heart and nerves, malfunction of the sexual organs and loss of vitality, rickets, tuberculosis, acidosis, excessive weight, constipation, improper digestion, pain, improper brain function, memory loss, ulceration, non-coagulation of the blood in wounds, eye cataracts, sinus and catarrhal infections, soft bones and teeth, improper gland and nerve action; too acid or too alkaline blood, insomnia, wrinkles, premature aging, sagging



muscles, skin and mouth disorders, nervous breakdown, diarrhea, anemia, graying hair, high blood pressure, fatty liver, and others.

The libel alleged also that the article was misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 1-4-60. Default—destruction.

**6068. Phal dentifrice and mouth wash.** (F.D.C. No. 43778. S. No. 48-685 P.)

QUANTITY: 7 display ctns., each containing 12 btl., at Palo Alto, Calif.

SHIPPED: 3-19-59, from Chicago, Ill., by S. P. Phalmo Co.

LABEL IN PART: (Ctn.) "Phal the prescription dentifrice & mouth wash \* \* \* 2909" and (btl.) "Phal a positive alkalizor active ingredients: Balanced physiological salts, sucaryl, calcium, (Cyclamate-Abbott) combined with oils and flavor \* \* \* 5 ozs."

ACCOMPANYING LABELING: (Leaflet attached to btl.) "Phal the prescription dentifrice" and (leaflet in ctn.) "Soluble tooth powder and mouth wash."

LIBELED: 10-26-59, N. Dist. Calif.

CHARGE: 502(a)—when shipped, the labeling contained false and misleading representations that the article was an adequate and effective treatment for bleeding gums, pyorrhea, postextraction care, all periodontal lesions, such as gingivitis, Vincent's stomatitis, and periodontoclasia.

DISPOSITION: 12-1-59. Default—destruction.

**6069. Crampeze Breather Bag (device).** (F.D.C. No. 43601. S. No. 56-741 P.)

QUANTITY: 25,000 plastic bags at Atlanta, Ga., in possession of James Thomas Smith.

SHIPPED: Pellets of Tenite polyethylene were shipped on 8-5-59, from Kingsport, Tenn.

LABEL IN PART: (Bag) "Crampeze Breather Bag 1. Take deep breath through nose; 2. Exhale in bags through mouth; 3. Inhale contents through nose; 4. Repeat five times; 5. If cramps persist continue treatment for five nights; 6. On reoccurrence of pain repeat treatment Crampeze."

ACCOMPANYING LABELING: Leaflets entitled "Cramps occurring in legs and feet can be greatly helped."

RESULTS OF INVESTIGATION: Examination showed the article to be an 8" x 14" clear plastic bag. The bags were manufactured locally in Georgia, from the pellets which had been shipped as described above.

The leaflets were prepared locally for the dealer.

LIBELED: 10-16-59, N. Dist. Ga.

CHARGE: 502(a)—while held for sale, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for cramps and pains in the legs and feet.

DISPOSITION: 1-6-60. Default—100 bags were delivered to the Food and Drug Administration and the remainder were destroyed.

**6070. Massage device.** (F.D.C. No. 41702. S. No. 11-440 P.)

QUANTITY: 21 individually cartoned devices at Philadelphia, Pa.

SHIPPED: 5-8-58, from Dearborn, Mich., by Relax-O-Therapy Equipment Co., Inc.

LABEL IN PART: (Metal plate) "Ther-Massage."

ACCOMPANYING LABELING: Folder entitled "Protect Your Health With Relax-O-Thermassage."

RESULTS OF INVESTIGATION: The device was a cushioned box containing a motor capable of providing vibrating motions.

LIBELED: 5-12-58, E. Dist. Pa.

CHARGE: 502(a)—when shipped, the labeling contained false and misleading representations that the device was an adequate and effective treatment for overcoming nervous tension, muscular stiffness, aching joints and muscles; increasing blood circulation; aiding the body to make use of its own protective and self healing powers; to rid the body of wastes, poisons, and foreign matter; to stimulate organs of purification and elimination, thereby freeing nerves, blood vessels, and lymph of obstructions; equalizing circulation throughout all parts of the body; restoring nerve energy through proper blood supply to diseased organs and tissues; overcoming insomnia, arthritic joints, neuritis, and lumbago; and providing effective figure control.

DISPOSITION: Relax-O-Therapy Equipment Co., Inc., Dearborn, Mich., appeared as claimant and denied that the device was misbranded. On 9-15-59, the Government filed written interrogatories. The claimant failed to answer the interrogatories and thereafter, on 3-16-60, a default decree of condemnation was entered and the article was destroyed.

6071. **Electro-Galvanic Apparatus.** (F.D.C. No. 41893. S. No. 6-580 P.)

QUANTITY: 50 devices and one carton of device accessories at Waltham, Mass.

SHIPPED: The devices were shipped on 8-20-56, from Hamburg, Germany, by Actien-Gesellschaft, and the accessories were shipped on 11-5-57, from Hamburg, Germany, by Caesar Kock Nachf.

LABEL IN PART: (Device) "Wolmuth-Zentrale \* \* \* Original-Apparat No. 125027" or "Elga 10093 Kosmetick Elga-Zentrale"; (ctn. of accessories) "Hammond & Montgomery \* \* \* Boston/USA."

ACCOMPANYING LABELING: Book entitled "Die Elektrogalvanische Heilkunde."

RESULTS OF INVESTIGATION: The article consisted of dry cells, a meter, and a variety of electrodes for applying galvanic current to all parts of the body.

LIBELED: 6-25-58, Dist. Mass.

CHARGE: 502(a)—when shipped and while held for sale, the labeling which accompanied the device contained false and misleading representations that the device was an adequate and effective treatment for conditions of the eyes, urinary tract, chest, feet, elbow, gallbladder, palate, joints, throat, heart, larynx, liver, stomach, rectum, nasal passages, ears, kidney, prostate, spinal cord, and vertebral column; asthma, bronchitis, hemorrhoids, varicose veins, goiter, paralysis, and pain.

DISPOSITION: On 5-5-59, George W. A. Hammond, Duxbury, Mass., appeared as claimant. Thereafter, on 9-9-59, the Government filed written interrogatories. After the claimant failed to answer the interrogatories, a default decree was entered on 2-1-60, and the device was destroyed.

6072. **Trim-Tone vibrating device.** (F.D.C. No. 41931. S. Nos. 31-552/5 P.)

QUANTITY: 150 Model SX devices, 12 Model T devices, 50 Model A devices, and 12 Model D devices, at Jamaica, N.Y., and 36 Model SX devices, 6 Model T devices, 6 Model A devices, and 6 Model D devices at Flushing, N.Y., in possession of B. Gertz, Inc.

SHIPPED: 6-6-58, from Knoxville, Tenn., by Figure-Tone Corp.

ACCOMPANYING LABELING: (Insert label) "Trim-Tone Slenderize The Easy Modern Way" or "Relax while you Reduce with a Figure-Tone The New Automatic Electric Vibrator" and newspaper advertisement tear sheets from a newspaper advertisement which appeared in the New York News on 6-15-58.

RESULTS OF INVESTIGATION: The device was constructed of mahogany and plywood, upholstered in polyethylene foam, covered with vinyl plastic, and equipped with an electric magnetic motor which provided vibration. The models varied in size and contour.

LIBELED: 7-18-58, E. Dist. N.Y.

CHARGE: 502(a)—when shipped and while held for sale, the labeling which accompanied the article contained false and misleading representations that the article was an adequate and effective treatment for removing ugly fat, invigorating tired muscles, reducing, relieving tension and physical aches and pains, spot reducing, increasing blood circulation, and trimming and firming the stomach, thighs, waist and hips.

DISPOSITION: On 8-15-58, after stipulation by the Government and Figure-Tone Corp., Knoxville, Tenn., the case was ordered transferred to the United States District Court for the Middle District of Tennessee. The Government filed written interrogatories which were answered by the claimant, Figure-Tone Corp. On 3-28-60, the claimant consented to a condemnation decree and the devices were subsequently destroyed.

**6073. Trim-Tone vibrating device.** (F.D.C. No. 42041. S. No. 26-444 P.)

QUANTITY: 48 devices at Des Moines, Iowa.

SHIPPED: 6-4-58, from Knoxville, Tenn., by Figure-Tone Corp.

ACCOMPANYING LABELING: Guarantee card folder entitled "Trim-Tone Figure Chart" and leaflets entitled "Relax and Keep Trim."

RESULTS OF INVESTIGATION: The device was of wood frame construction, upholstered with polyethylene foam, covered with vinyl plastic, and contained an electromagnetic motor providing vibration.

LIBELED: 7-7-58, S. Dist. Iowa.

CHARGE: 502(a)—when shipped, the labeling which accompanied the article contained false and misleading representations that the device was an adequate and effective treatment for getting rid of ugly fat without diets or drugs, relieving nervous tension, physical aches and pains, increasing "lazy circulation," and for reducing weight and trimming the figure.

DISPOSITION: On 8-13-58, after stipulation by the Government and Figure-Tone Corp., Knoxville, Tenn., the case was ordered removed to the United States District Court for the Middle District of Tennessee. The Government filed written interrogatories which were answered by the claimant, Figure-Tone Corp. On 3-28-60, the claimant consented to a condemnation decree and the devices were subsequently destroyed.

**6074. Iona Rotary Massager.** (F.D.C. No. 43025. S. No. 51-819 P.)

QUANTITY: 97 individually cartoned devices at Minneapolis, Minn.

SHIPPED: 4-1-59, from Manchester, Conn., by Iona Mfg. Co.

LABEL IN PART: (Tag on device) "Rotary Iona Massager \* \* \* Iona Electric Rotary Massager."



ACCOMPANYING LABELING: Leaflet in carton entitled "Enjoy Your Iona Motorized Rotary Massager" and newspaper tear sheets.

RESULTS OF INVESTIGATION: The article was a rigid upholstered cushion-type device containing an electric motor capable of providing vibrations.

Newspaper tear sheets had been prepared by the dealer from a newspaper mat received from the shipper.

LIBELED: 5-22-59, Dist. Minn.

CHARGE: 502(a)—when shipped and while held for sale, the labeling which accompanied the article contained false and misleading representations that the article was an adequate and effective treatment for moulding and firming flabby muscles and tissues; dissolving tensions, jangled nerves, and irritability; providing immediate relief and lasting benefit for backache; and for weight reducing.

DISPOSITION: 3-22-60. Consent—claimed by Iona Mfg. Co. and relabeled.

**6075. Sonus Film-O-Sonic device.** (F.D.C. No. 43276. S. No. 73-661 P.)

QUANTITY: 2 devices at Beaumont, Tex.

SHIPPED: 7-9-58, from Lynwood, Calif., by Sonus Research Products Co.

LABEL IN PART: "Sonus Film-O-Sonic."

ACCOMPANYING LABELING: Pamphlets entitled "Facts, Figures" and "Film-O-Sonic 105."

RESULTS OF INVESTIGATION: The article was a box-type cabinet containing a chassis consisting of a continuous cycle tape play-back mechanism, and amplifier, transformer unit and electrode pads. The chassis contained no vibrator nor sound wave mechanism.

LIBELED: 6-30-59, E. Dist. Tex.

CHARGE: 502(a)—when shipped, the labeling which accompanied the article contained false and misleading representations that the article was capable of diagnosing and effectively treating pathological conditions of the head, lungs, heart, stomach, sinuses, gallbladder, spleen, appendix, ovaries, prostate, and spine; ulcers, cancer, cataracts of the eyes, and other germ diseases; that the article was capable of helping the system build up immunity to any disease with which specific organisms may be associated; and that application of the device would strengthen and stimulate the various muscle groups of the body.

DISPOSITION: 1-22-60. Consent—delivered to the Food and Drug Administration.

**6076. Slenderette vibrating device.** (F.D.C. No. 42552. S. No. 29-527 P.)

QUANTITY: 17 devices, individually cartoned, at Jackson, Miss.

SHIPPED: 10-2-58 and 10-17-58, from Fort Worth, Tex., by Latson, Inc.

LABEL IN PART: "Slenderette Mfg. and Dist. by Latson, Inc., 3041 Cockrell St., Fort Worth, Texas \* \* \* Serial No. 2489."

ACCOMPANYING LABELING: Booklet entitled "The Look You Long For \* \* \* Achieved with Slenderette."

RESULTS OF INVESTIGATION: The article was a table or lounge-type vibrator device. The electric motor was contained in a housing on which two vibrating cushion-type pads were mounted. Tubular extensions from the motor housing supported head and leg rests.

**LIBELED:** 12-5-58, S. Dist. Miss.

**CHARGE:** 502(a)—when shipped, the device label and the labeling which accompanied the article contained false and misleading representations that it was an adequate and effective treatment for relocating the stomach into normal position by stretching the spine and lifting the diaphragm; realigning the bone structure to correct the posture; correcting pelvic dip and stooped shoulders; increasing circulation and overcoming poor elimination; tightening up loose and flabby muscles; firming the tissues; and reducing weight and slenderizing the figure.

**DISPOSITION:** 11-12-59. Consent—claimed by S. L. Varnado, Jackson, Miss., and brought into compliance with the law by destruction of the booklets and labels.

**6077. Wonder Ease device.** (F.D.C. No. 43301. S. No. 52-929 P.)

**QUANTITY:** 46 individually cartoned devices at North Hollywood, Calif., in possession of Wonder Ease Co.

**SHIPPED:** 3-19-59 and 4-14-59, from Denver, Colo., by Cyclo Mfg. Co.

**LABEL IN PART:** (Device) "Cyclo Wonder Ease Model 5 Denver, Colo. \* \* \* Serial No. 14671."

**ACCOMPANYING LABELING:** Booklets enclosed in each carton entitled "Wonder Ease Slenderizer Instruction Booklet," also other booklets entitled "Beyond the Magic Door," and a number of salesmen's manuals and diet and calorie charts entitled "Suggested Diet" and "Wonder Ease Calorie Chart."

**RESULTS OF INVESTIGATION:** All of the accompanying labeling was printed in Los Angeles, Calif., with the exception of the instruction booklets.

The device consisted of a motor to which was attached two soft rubber discs. Vibration was obtained by eccentric rotation of the two discs in a vertical plane. The motor was attached to a tubular aluminum frame in such manner that it could slide up or down so that different areas of the body could be reached for massage. The motor could also be removed and held in the hand while massaging parts of the body which could not be reached while the motor was attached to the frame. The aluminum frame holding the motor was mounted on a door by means of clamps and suction cups. For massaging the feet the motor could be placed on the floor and the feet placed against the vibrator.

**LIBELED:** 7-16-59, S. Dist. Calif.

**CHARGE:** 502(a)—when shipped and while held for sale, the labeling accompanying the article contained false and misleading representations that the article was an adequate and effective treatment for slenderizing, reducing weight, trimming inches "from hips, tummy, and legs with no strenuous diet," spot reducing, overcoming nervous tension, improving circulation, overcoming neuritis and rheumatism, providing a clear and radiant complexion, and providing general benefits to the entire body.

**DISPOSITION:** 10-28-59. Consent—claimed by Cyclo Mfg. Co. and relabeled.

**6078. Furow health pillow.** (F.D.C. No. 43359. S. No. 48-879 P.)

**QUANTITY:** 184 individually cartoned plastic-covered pillows at San Francisco, Calif.

**SHIPPED:** 11-5-58 and 6-26-59, from Osaka, Japan, by Osaka Kairiku Bussan Co., Ltd.

**LABEL IN PART:** (Ctn. and tag on pillow) "Furow Health Pillow No. 120 [or other model numbers] Made in Japan."

**ACCOMPANYING LABELING:** Brochure entitled "Preserve Your Youth and Healthfulness" and leaflet entitled "For Your Sound Sleep Bringing Health & Success."

**RESULTS OF INVESTIGATION:** The pillows consisted of various models identified as 43/Model 120; 24/Model 150; 48/Model 160; 24/Model 180; 6/Model 190; 4/Model 195; 24/Model 300; and 11/Model 350.

Examination of Model 120 showed that it was a mat made of pieces of white china strung together with plastic-covered thread. It was 13 inches long,  $6\frac{1}{2}$  inches wide, and  $1\frac{1}{4}$  inches thick. The china pieces were backed with a piece of thin, flexible, blue plastic plate with oval cutouts. Back of this plate was a double thickness of green-covered plastic covered with woven wire to provide for cushioning and air circulation. The mat had plastic cords resembling light gauge electric cord attached to the top and bottom edges.

Models 160, 195, 300, and 350 were mounted on ventilated latex rubber.

**LIBELED:** 8-25-59, N. Dist. Calif.

**CHARGE:** 502(a)—when shipped, the labeling which accompanied the article contained false and misleading representations that the article was an adequate and effective treatment for headache, sleeplessness, hysteria, stiff shoulder, neurosis, "prinnipus," apoplexy, and hypertension; that it would preserve one's health and youthfulness, calm nerves, regulate blood circulation, and make the brain clear.

**DISPOSITION:** 10-27-59. Consent—claimed by F. M. Nonaka Co., Inc., t/a Crown Import Co., San Francisco, Calif., and relabeled.

**6079. Electric massage pillow.** (F.D.C. No. 43399. S. No. 23-181 P.)

**QUANTITY:** 1,714 individually cartoned devices at Los Angeles, Calif.

**SHIPPED:** 6-2-59 and 6-8-59, from Boston, Mass., by the Bandwagon Mfg. Co.

**LABEL IN PART:** (Leaflet in ctn.) "Trim Electric Massage Pillow \* \* \* Bandwagon, Boston 10, Mass."

**RESULTS OF INVESTIGATION:** Examination showed the article to be a rectangular-shaped corduroy-covered foam rubber cushion about  $10\frac{1}{2}$  x  $10\frac{1}{2}$  x  $3\frac{1}{2}$  inches in size, containing an electrically operated vibrating mechanism.

**LIBELED:** 7-24-59, S. Dist. Calif.

**CHARGE:** 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for firming the figure; firming flabby muscles; toning sagging muscles; as an aid in reducing; to restore normal circulation; to rid the abdomen and hips of excess flabbiness; and to bring about renewed vigor.

**DISPOSITION:** 8-17-59. Consent—claimed by Sunset House Distributing Corp. of Los Angeles, Calif., and relabeled.

**6080. Filtex vacuum cleaner.** (F.D.C. No. 43363. S. No. 65-146 P.)

**QUANTITY:** 12 individually cartoned devices at Salt Lake City, Utah.

**SHIPPED:** 5-19-59, from Los Angeles, Calif., by Filtex Corp.

**LABEL IN PART:** (Device) "MODEL 19-B SERIAL NUMBER 95 485 (THRU 95 496) THE FILTEX CORPORATION, 417-423 EAST 15TH STREET, LOS ANGELES 15, CALIF." and (ctn.) "HYGIENIC AIR PURI-



**FIER FILTEX \* \* \* THE FILTEX CORP., 417-423 E. 15TH St. LOS ANGELES 15, CALIF."**

**ACCOMPANYING LABELING:** An instruction booklet entitled "FILTEX AMERICA'S MOST MODERN HOME CLEANING MACHINES"; and leaflets entitled "PROTECT YOUR FAMILY THE FILTEX WAY," "PROTECT YOUR FAMILY FROM DANGEROUS, DISEASE-BREEDING DUST GERMS," and "THE AMAZING FILTEX."

**RESULTS OF INVESTIGATION:** The article was a cannister-type, electrically operated, vacuum cleaner with a filter and attachments.

**LIBELED:** 8-31-59, Dist. Utah.

**CHARGE:** 502(a)—when shipped, the labeling contained false and misleading representations that the article was capable of preventing staphylococcus infections such as boils, abscesses, osteomyelitis (bone infection), etc.; streptococcus infections such as "strep" throat, scarlet fever, erysipelas, tonsillitis, etc.; that it would remove all disease germs from the home, keep the home germ-free, cut down sickness in the home, prevent spreading of infections, safeguard the childrens' health, and protect against disease-producing germs causing tuberculosis, pneumonia, influenza, and the common cold.

**DISPOSITION:** 11-27-59. Consent—claimed by Filtext Corp., and relabeled.

## INDEX TO NOTICES OF JUDGMENT D.D.N.J. NOS. 6041 TO 6080

### PRODUCTS

	N.J. No.		N.J. No.
Arthritis, remedy for. <i>See</i>		Diabetes, remedy for-----	6061, 6063
Rheumatism, remedy for.		Dur-Den-Col-----	6045
Aureomycin ointment, Lederle--	6050	Electric massage pillow-----	6079
Bellergal tablets-----	6050	Electro-Galvanic Apparatus----	6071
Bipanzyne tablets-----	6061	Energol Germ Oil Concentrate--	6059
Blue Seal Mash-----	6056	Equanil tablets-----	6050
Bursitis, remedy for. <i>See</i>		imitation-----	6041
Rheumatism, remedy for.		Filtex vacuum cleaner-----	6080
Canker, remedy for-----	6062	Farrow health pillow-----	6078
Canker-Eze-----	6062	Gingivitis, remedy for-----	6068
Chick Starter-----	6056	Gout, remedy for. <i>See</i>	
Chloramphenicol capsules-----	6043	Rheumatism, remedy for.	
Chlorhydrate De Neohetramine--	6043	Hemorrhoids, remedy for-----	6046
Chloroform-----	6050	Iodine preparation-----	6060
Clotin-----	6055	Iona Rotary Massager-----	6074
Cosmetics (subject to the drug		Kay-San Ointment-----	6051
provisions of the Act)--	6048, 6068	Kelp tablets-----	6066
Crampeze Breather Bag (de-		Ledercillin Troches-----	6050
vice)-----	6069	Lobie #1 tablets-----	6052
Davis Union remedy-----	6063	Lumbago, remedy for. <i>See</i>	
Del-Caps timed disintegration		Rheumatism, remedy for.	
capsules-----	6054	Massage device-----	<sup>1</sup> 6070
Dentifrice and mouth wash,		Medicated feed-----	6044
Phal-----	6068	Meprobamate tablets-----	6042
Dermo-G ointment-----	6046	Miltown tablets, imitation-----	6041
Devices-----	<sup>1</sup> 6069-6080		
Dexamyl tablets-----	6050		

<sup>1</sup> (6070) Seizure contested.

	N.J. No.		N.J. No.
Neuralgia, remedy for. <i>See</i>		Skin disorders, remedies for...	6046-
Rheumatism, remedy for.			6048, 6051
Neuritis, remedy for. <i>See</i> Rheu-		Slenderette vibrating device....	6076
matism, remedy for.		Sonus Film-O-Sonic device....	6075
No. 66 ointment.....	6050	Stan Dispenstick.....	6048
Nux vomica NF.....	6050	Styk.....	6048
Obocell tablets.....	6050	Supra Vite Special Food Supple-	
Ointments.....	6046, 6050, 6051	ment.....	6049
Phal dentifrice and mouth wash.	6068	Vitamin E Perles.....	6049
Penicillin G ointment, procaine,		Snydrox Methamphetamine Hy-	
Ledercillin.....	6050	drochloride tablets.....	6050
potassium tablets.....	6050	Terramycin tablets.....	6043
tablets.....	6050	Testone Wheat Germ Oil cap-	
V, Pen-Vee suspension benza-		sules.....	6065
thine.....	6043	Tranquilizers.....	6041, 6042
Poultry feed, medicated.....	6056	Trim-Tone vibrating device....	6072,
Procaine hydrochloride injec-			6073
tion.....	6053	Try-Phetamine Compound tab-	
penicillin G ointment, Leder-		lets.....	6050
cillin.....	6050	Vacuum cleaner, Filtex.....	6080
Pyorrhea, remedy for.....	6068	Veterinary preparations.....	6044,
Reducing preparation.....	6058		6055, 6056, 6060
devices... 6072-6074, 6076, 6077,	6079	Vi-Aquamin Therapeutic cap-	
Rejuvenator.....	6065	sules.....	6043
Rheumatism, remedy for.....	6063	Vibrating devices..... <sup>1</sup>	6070.
device.....	6077		6072-6074, 6076, 6077, 6079
Sciatica, remedy for. <i>See</i> Rheu-		Vitamin preparations.....	6049, 6055.
matism, remedy for.			6057, 6059, 6064
7/Eleven Health tablets.....	6067	Wheat Germ Oil capsules, Tes-	
Shai Skin-Trete.....	6047	tone.....	6065
Silhouettes capsules.....	6058	Wonder Ease device.....	6077
		Zest Capsules.....	6064

## SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

	N.J. No.		N.J. No.
Actien-Gesellschaft		Canal Medical Products. <i>See</i>	
Electro-Galvanic Apparatus....	6071	Silfan, Morris.	
Allied Biochemical Laboratories:		Canker-Eze Co.:	
procaine hydrochloride injec-		Canker-Eze.....	6062
tion.....	6053	Cyclo Mfg. Co.:	
Anderson, Martin, Co.:		Wonder Ease device.....	6077
iodine preparation.....	6060	Delmar Pharmacal Corp.:	
Apothecary Products Co.:		Del-Caps timed disintegration	
various vitamin and mineral		capsules.....	6054
tablets.....	6057	Dermo-G, Inc.:	
Bandwagon Mfg. Co.:		Dermo-G ointment.....	6046
electric massage pillow.....	6079	Figure-Tone Corp.:	
Blau, Seymour:		Trim-Tone vibrating device....	6072,
imitation Miltown tablets and			6073
imitation Equanil tablets....	6041	Filtex Corp.:	
		Filtex vacuum cleaner.....	6080

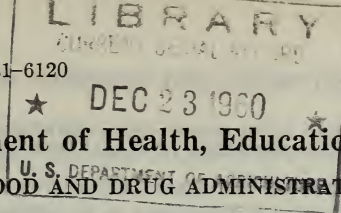
<sup>1</sup> (6070) Seizure contested.

	N.J. No.		N.J. No.
Fultondale Sundry Store. <i>See</i>		Roberts, J. H.:	
Mickwee, S. K.		Lobie #1 tablets-----	6052
Gertz, B., Inc.:		Rosal Laboratories, Ltd.:	
Trim-Tone vibrating device---	6072	Shai Skin-Trete-----	6047
Gland-O-Lac Co.:		Royalin Co., Inc.:	
Clotin-----	6055	Zest capsules-----	6064
Grain Processing Corp.:		Salude Laboratories, Inc.:	
medicated feed-----	6044	imitation Miltown tablets and	
Hoffman, Bob:		imitation Equanil tablets---	6041
Energol Germ Oil Concentrate--	6059	Savitch, Leo:	
Howe Products, Inc.:		Testone Wheat Germ Oil cap-	
various vitamin and mineral		sules-----	6065
tablets-----	6057	Sentral Laboratories, Inc.:	
Inorganic Bioelements, Inc.:		Lobie #1 tablets-----	6052
iodine preparation-----	6060	Service Industries:	
Iona Mfg. Co.:		7/Eleven Health tablets-----	6067
Iona Rotary Massager-----	6074	Seward Laboratories, Inc.:	
Jan Laboratories:		Testone Wheat Germ Oil cap-	
meprobamate tablets-----	6042	sules-----	6065
Johns Distributing Co.:		Silfan, Morris:	
Davis Union remedy-----	6063	Testone Wheat Germ Oil cap-	
Latson, Inc.:		sules-----	6065
Slenderette vibrating device--	6076	Smith, J. T.:	
Lavin, Edward:		Crampeze Breather Bag (de-	
meprobamate tablets-----	6042	vice)-----	6069
Levin, Jerry:		Sonus Research Products Co.:	
meprobamate tablets-----	6042	Sonus Film-O-Sonic device---	6075
Mickwee, S. K.:		Southwest Pharmaceutical Corp.,	
various prescription drugs----	6050	Inc.:	
Millican, S. E.:		Dur-Den-Col-----	6045
Supra Vite Special Food		Spandau, Ludwig:	
Supplement and Supra Vite		imitation Miltown tablets and	
Vitamin E Perles-----	6049	imitation Equanil tablets---	6041
N.D.L., Inc.:		Stanley Research Corp.:	
Silhouettes capsules-----	6058	Stan Dispenstick and Stan	
Nachf, C. K.:		Styk-----	6048
Electro-Galvanic Apparatus---	6071	Stenton Laboratories, Inc.:	
New York Medical Products. <i>See</i>		Kay-San ointment-----	6051
Silfan, Morris.		Veltex Co.:	
Osaka Kairiku Bussan Co., Ltd.:		Bipanzyme tablets-----	6061
Furrow health pillow-----	6078	Webster, W. N.:	
Phalmo, S. P., Co.:		medicated poultry feed-----	6056
Phal dentifrice and mouth		Webster, H. K., Co.:	
wash-----	6068	medicated poultry feed-----	6056
Private Labels, Inc.:		Wonder Ease Co.:	
Stan Dispenstick and Stan		Wonder Ease device-----	6077
Styk-----	6048	York Barbell Co.:	
Pruitt, T. D.:		Energol Germ Oil Concen-	
kelp tablets-----	6066	trate-----	6059
Relax-O-Therapy Equipment Co.,			
Inc.:			
massage device-----	<sup>1</sup> 6070		

<sup>1</sup> (6070) Seizure contested.



32nd



U.S. Department of Health, Education, and Welfare  
U. S. DEPARTMENT OF HEALTH, EDUCATION AND WELFARE  
FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD,  
DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug and Cosmetic Act]

6081-6120

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were adulterated or misbranded within the meaning of the Act when introduced into and while in interstate commerce or while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings in which decrees of condemnation were entered after default or consent and (2) a criminal proceeding terminated upon a judgment of guilty after trial. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation, and the criminal proceedings are against the *firms* or *individuals* charged to be responsible for violations.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D.C., November 25, 1960.

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\*For omission of, or unsatisfactory, ingredients statements, see Nos. 6088, 6090, 6094, 6106; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 6081, 6088, 6090, 6094, 6097; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 6088, 6094, 6119; cosmetic, actionable under the drug provisions of the Act, No. 6094.

**SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN  
VIOLATIONS REPORTED IN D.D.N.J. NOS. 6081-6120**

*Adulteration*, Section 501(b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopoeia or National Formulary), and its strength differed from, or its quality and purity fell below, the standard set forth in such compendium; and Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength differed from, or its quality and purity fell below, that which it purported or was represented to possess.

*Misbranding*, Section 502(a), the labeling of the article was false and misleading; Section 502(b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; Section 502(e), the article was a drug not designated solely by a name recognized in an official compendium, and its label failed to bear (1) the common or usual name of the drug, and (2) the drug was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient; Section 502(f), the labeling of the article failed to bear (1) adequate directions for use, and (2) adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods of duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 502(j), the article was dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof; Section 502(l), the article consisted in part of penicillin and dihydrostreptomycin, and the article was not from a batch with respect to which a certificate or release had been issued pursuant to Section 507; and Section 503(b)(4), the article was subject to 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

*New-drug violation*, Section 505(a), the article was a new drug within the meaning of Section 201(p), which was introduced into interstate commerce, and an application filed pursuant to Section 505(b) was not effective with respect to such drug.

**DRUG AND DEVICES ACTIONABLE BECAUSE OF POTENTIAL DANGER  
WHEN USED ACCORDING TO DIRECTIONS**

**6081. Arthritis remedy.** (F.D.C. No. 43531. S. No. 5-699 P.)

**QUANTITY:** 20 2-oz. btls. at Martinsville, Va.

**SHIPPED:** 8-20-59, from Price, N.C., by Myrtle Chemical Co.

**LABEL IN PART:** "Arthritis Remedy \* \* \* Manufactured by Myrtle Chemical Co., 802 Princeton Street, Martinsville, Va. \* \* \* Ingredients: Mono Butyl Ether, Synthetic Joint Fluid, Bichromatic Potash, Antimony, Trichloride and Tergitol."

**RESULTS OF INVESTIGATION:** Examination showed that the article contained antimony chloride, diethylene glycol monobutyl ether, and Tergitol (a wetting agent). No potassium bichromate was present.

**LIBELED:** 9-18-59, W. Dist. Va.

**CHARGE:** 502(a)—when shipped, the name "Arthritis Remedy," and the label statement "Ingredients: \* \* \* Bichromatic Potash" were false and misleading



as applied to an article which was not an adequate and effective treatment for arthritis, and which contained no potassium bichromate; 502(b) (2)—the article failed to bear a label containing an accurate statement of the quantity of contents; 502(j)—the article was dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in its labeling; and 505(a)—the article was a new drug within the meaning of the law, and an application filed pursuant to law was not effective with respect to the article.

DISPOSITION: 11-3-59. Default—destruction.

**6082. Allure bust development device.** (F.D.C. No. 43795. S. No. 23-186 P.)

QUANTITY: 4 crated devices at Los Angeles, Calif.

SHIPPED: 10-6-59, from Tulsa, Okla., by Mrs. Mabel Ward.

LABEL IN PART: (Device) "Allure Mfd. by Allure Incorporated, Hollywood, California, Model 1097, Serial No. 7959 [or other numbers]."

RESULTS OF INVESTIGATION: The article consisted of rubber-ringed plastic cups of various sizes which had small openings for connection to rubber hoses attached to an air compressor or electrically operated pump. Attached to the compressor was a pressure regulator, vacuum gauge, and a valve to regulate the amount of vacuum produced in each of the two breast cups while in use. The plastic cups were pressed over the breasts against the chest and the rubber-ringed edge formed an airtight seal. The air compressor was then operated to form a vacuum inside the cups to exercise the breasts by contraction and relaxation. The air compressor and accessory equipment were contained in a metal cabinet 36" x 22" x 18".

LIBELED: 11-6-59, S. Dist. Calif.

CHARGE: 502(f) (1)—when shipped, the labeling of the article failed to bear adequate directions for use for the purpose for which it was intended, namely, for developing the human breasts; and 502(j)—the article was dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in its labeling.

DISPOSITION: 12-3-59. Default—destruction.

**6083. Allure bust development device.** (F.D.C. No. 43331. S. No. 53-228 P.)

QUANTITY: 2 devices at Phoenix, Ariz., in possession of Allure Salon.

SHIPPED: During December 1958, from Hollywood, Calif., by Allure, Inc.

LABEL IN PART: "Allure Mfd. Allure Incorporated, Hollywood, Calif. Model 1053 [or "1052"] Serial No. 9358 [or "82058"]" and "Allure Inc. Switzer Machines."

ACCOMPANYING LABELING: White cards containing the words "I the undersigned do hereby request 'Allure Salon' to administer to me that certain treatment known as 'Switzer Method for Bust Development.'"; pink colored folders headed "Free Consultation and Demonstration."; and leaflet entitled "Be Proud of Your Bust."

RESULTS OF INVESTIGATION: The article consisted of rubber-ringed plastic cups of various sizes which have small openings for connection to rubber hoses attached to an air compressor or electrically operated pump. Attached to the compressor is a pressure regulator and a vacuum gauge, and a valve to regulate the amount of vacuum produced in each of the two breast cups while in use. The plastic cups are pressed over the breasts against the chest and the



rubber-ringed edge forms an airtight seal. The air compressor is then operated to form a vacuum inside the cups to exercise the breasts by contraction and relaxation. The air compressor and accessory equipment are contained in a metal cabinet 36" x 22" x 18".

The pink-colored folders were printed locally for the dealer.

**LIBELED:** 8-3-59, Dist. Ariz.; libel amended 9-10-59.

**CHARGE:** 502(a)—when shipped and while held for sale, the labeling of the article contained false and misleading representations that the article was a safe, adequate and effective treatment for increasing the size of the breasts, for underdeveloped, sagging breasts, and to increase circulation to feed the underfed breast tissues so that they would grow naturally and normally; 502(f) (1)—the labeling of the article failed to bear adequate directions for use; 502(j)—the article was dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.

**DISPOSITION:** 12-3-59. Default—delivered to the Food and Drug Administration.

**6084. Allure bust development device.** (F.D.C. No. 43605. S. No. 82-812 P.)

**QUANTITY:** 3 devices at Kansas City, Mo.

**SHIPPED:** 7-10-59 and 7-14-59, from Alhambra, Calif., by Allure, Inc.

**LABEL IN PART:** (Front panel) "Allure Inc. Switzer Machine" and (back panel) "Allure Mfd. by Allure Incorporated Hollywood, Calif. Model 1100 [or "1099" or "1098"] Serial No. 7959."

**ACCOMPANYING LABELING:** Booklet entitled "Allure."

**RESULTS OF INVESTIGATION:** The article consisted of rubber-ringed plastic cups of various sizes which had small openings for connection to rubber hoses attached to an air compressor or electrically operated pump. Attached to the compressor was a pressure regulator, a vacuum gauge, and a valve to regulate the amount of vacuum produced in each of the two breast cups while in use. The plastic cups were pressed over the breasts against the chest and the rubber-ringed edge formed an airtight seal. The air compressor was then operated to form a vacuum inside the cups to exercise the breasts by contraction and relaxation. The air compressor and accessory equipment were contained in a metal cabinet 35" x 22" x 18".

**LIBELED:** On or about 10-20-59, W. Dist. Mo.

**CHARGE:** 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was a safe, adequate and effective treatment for increasing the size of the breasts; for under-developed, sagging breasts; for developing the breasts; improving the appearance of the breasts; inverted nipples; and to increase circulation to feed the underfed breast tissues so that they would grow naturally and normally; that it was capable of bringing about complete bust correction and a beautiful bust line; that it would restore youth, beauty, and glamour and that its use would prevent cancer in the breasts; 502(f) (1)—the labeling of the article failed to bear adequate directions for use; and 502(j)—the article was dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in its labeling.

**DISPOSITION:** 12-7-59. Default—delivered to the Food and Drug Administration.

## NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION\*

6085. **Pabacaine.** (F.D.C. No. 44147. S. No. 66-712 P.)

QUANTITY: 1,550 ampuls at Los Angeles, Calif., in possession of Brown Pharmaceutical Co.

SHIPPED: 10-19-59, from Philadelphia, Pa., by the Philadelphia Ampule Laboratories, Inc.

LABEL IN PART: (Ampul) "5 cc Ampule Pabacaine each ampule contains: Pabacaine 100 mg. Ascorbic Acid 50 mg. \* \* \* Glutamic Acid 50 mg \* \* \* Exclusive U.S. Distributors—The Brown Pharmaceutical Co., Los Angeles, Calif. 9966."

ACCOMPANYING LABELING: Brochures entitled "Research On The Use of H3 In The Treatment Of Old Age And Other Diseases."

RESULTS OF INVESTIGATION: The brochures were printed locally for the dealer.

LIBELED: 12-31-59, S. Dist. Calif.

CHARGE: 502(a)—while held for sale, the labeling which accompanied the article contained statements that the article appeared to make old people younger than their natural age; usually they experienced a marked improvement in general health; some elderly patients found their new hair growth was youthfully dark in color; in certain kinds of baldness, hair growth was restored dramatically; often the patients showed a marked improvement in their skin texture; a large percentage became strong enough to resume work again; many people crippled with arthritis had been strikingly helped; heart action and blood circulation were usually much improved; treatment had cured many cases of stomach ulcers; profound effects were shown in the central nervous system, with some men and women achieving greater improvement in eyesight and hearing; the brain functions frequently improved, with most elderly patients exhibiting notable strengthening of memory and attention; and treatment was also given to younger men and women suffering from arthritis, neuralgia, stomach ulcers, premature baldness, and other ailments; which statements were false and misleading since the article was not capable of fulfilling the promises of benefit stated and implied; 505(a)—the article was a new drug within the meaning of the law, since its safety for use in the treatment of old age and other conditions mentioned in its accompanying labeling had not been established and an application filed pursuant to the law was not effective with respect to such drug.

DISPOSITION: 1-26-60. Default—destruction.

6086. **Hope's Worm-Rid.** (F.D.C. No. 43458. S. No. 69-683 P.)

QUANTITY: 12 cases, each containing 1 display ctn. which contained 12 btls. at Minneapolis, Minn.

SHIPPED: 9-4-59, from Clayton, Mo., by Hope Co.

LABEL IN PART: (Btl.) "Hope's Worm-Rid 4 ounces \* \* \* A Safe \* \* \* Syrup for the eradication of Pin and Roundworms Each Teaspoonful (5 cc). Contains: Piperazine Citrate Equivalent to 500 mg. Piperazine Hexahydrate \* \* \* The Hope Company, Clayton 5, Missouri."

LIBELED: 10-1-59, Dist. Minn.

\*See also No. 6081.

CHARGE: 505(a)—the article was a new drug which may not be introduced into interstate commerce since an application filed pursuant to law was not effective with respect to such drug.

DISPOSITION: 11-13-59. Default—destruction.

## DRUG REQUIRING CERTIFICATE OR RELEASE, FOR WHICH NONE HAD BEEN ISSUED

### DRUG FOR VETERINARY USE

6087. Entero-Sol Powder. (F.D.C. No. 43323. S. No. 71-708 P.)

QUANTITY: 10 cases, 12 btls. each, at Gainesville, Ga.

SHIPPED: 5-25-59, from Vineland, N.J., by Eastern Laboratories, Inc.

LABEL IN PART: (Btl.) "Rollins Entero-Sol Powder For the treatment of Enteritis, Air-Sac, Colds and Blue Comb in Chickens and Turkeys \* \* \* Contents 156 Gms. Each Pound Contains: 24,000,000 units of Penicillin G. Potassium 24,000 mg. of Dihydrostreptomycin Base as sulphate, and 3,600 mg. of Menadione Sodium Bisulfite (Synthetic Vitamin K) In addition each pound contains: \* \* \* Manufactured for Ben C. Rollins Company 602 Grove Street, Gainesville, Georgia."

LIBELED: 8-4-59, N. Dist. Ga.

CHARGE: 502(a)—when shipped, the label of the article contained false and misleading representations that the article was an adequate and effective treatment for colds in chickens and turkeys; and 502(1)—the article consisted in part of penicillin and dihydrostreptomycin and it was not from a batch with respect to which a certificate or release had been issued.

DISPOSITION: 9-23-59. Default—destruction.

## DRUG IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

6088. Dextro-amphetamine sulfate tablets and amphetamine sulfate tablets. (F.D.C. No. 43391. S. Nos. 73-809/10 P.)

QUANTITY: 5 1,000-tablet btls. at Bay Saint Louis, Miss.

SHIPPED: Prior to 7-7-59, from outside the State of Mississippi.

RESULTS OF INVESTIGATION: The bottles were unlabeled. Analysis showed that 3 bottles contained *dextro-amphetamine sulfate tablets* and 2 bottles contained *amphetamine sulfate tablets*.

LIBELED: 7-13-59, S. Dist. Miss.

CHARGE: 502(b)—while held for sale, the article failed to bear (1) a label containing the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents in terms of count; 502(e) (1)—the label failed to bear the common or usual name of the drug; 502(f) (1)—the label of the article failed to bear adequate directions for use and it was not exempt from such requirement since it was in possession of a person or persons not authorized to dispense a prescription drug; and 503(b) (4)—the label of the article failed to bear the statement "Caution—Federal law prohibits dispensing without prescription."

DISPOSITION: 8-18-59. Default—destruction.



DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR  
ADEQUATE DIRECTIONS OR WARNING STATEMENTS

DRUGS FOR HUMAN USE\*

6089. Napier's 14 & 10 Vitamins-Minerals tablets, Napier's Special Formula tablets, Napier's Inhalant & Rubbing Oil, and Napier's Family Salve. (F.D.C. No. 43099. S. Nos. 25-277/80 P.)

INFORMATION FILED: 9-14-59, N. Dist. Iowa, against Don A. Napier, Tahlequah, Okla.

ALLEGED VIOLATION: On 9-11-58, the defendant, in the course of a sales talk at the Clay County Fair, Spencer, Iowa, made oral representations holding out *Napier's 14 & 10 Vitamins-Minerals tablets* (count 1), *Napier's Special Formula tablets* (count 3), *Napier's Inhalant & Rubbing Oil* (count 5), and *Napier's Family Salve* (count 6), as treatments for the diseases, symptoms, and conditions set forth below, which acts resulted in the article being misbranded while held for sale in violation of 502(f) (1).

The information alleged also that the defendant caused *Napier's 14 & 10 Vitamins-Minerals tablets* (count 2) and *Napier's Special Formula tablets* (count 4) to be accompanied by labeling, namely, the booklets and leaflets referred to below, which acts resulted in the articles being misbranded while held for sale in violation of 502(a).

LABEL IN PART: "NAPIER'S 14 & 10 (Improved) VITAMINS-MINERALS 60 Tablets—30 day supply Prepared for CHIEF D. A. NAPIER R.R. #3 · Tahlequah, Okla."; "100 Tablets NAPIER'S Special Formula E.P. A high potency dietary supplement furnishing a wide range of vitamins and minerals Distributed by CHIEF D. A. NAPIER R.R. #3 · Tahlequah, Okla."; NAPIER'S Inhalant & Rubbing Oil. Relieve Symptoms of COLDS by inhaling also use as a RUBBING OIL for soreness in the body due to COLDS and FATIGUE Active Ingredients: Eucalyptus Oil, Menthol, Peppermint Oil, Thymol, Camphor Contents 1 Fl. Oz. CHIEF D. A. NAPIER R.R. 3 Tahlequah, Okla."; and "CONTENTS 2 Fl. Ozs. NAPIER'S FAMILY SALVE. Active Ingredients: Methyl Salicylate, Oil Pine Tar and Balsam Peru in a Petrolatum base. DIRECTIONS: CHIEF D. A. NAPIER R.R. 3 TAHLEQUAH, OKLA."

ACCOMPANYING LABELING: Booklet entitled "Napier's Health Book" and a leaflet entitled "How vitamins and minerals help the whole family."

CHARGE: 502(a)—the labeling which accompanied the *Napier's 14 & 10 Vitamins-Minerals tablets* and *Napier's Special Formula tablets* contained false and misleading representations that such articles were adequate and effective to insure radiant health, and to prevent and treat practically all diseases and pathological conditions of man, including tuberculosis, heart disease, liver and kidney disorders, gout, jaundice, skin diseases, indigestion, sexual weakness or impotence, mental deficiency, diabetes, catarrh, sores that do not heal, arthritis, rheumatism, chronic bronchitis, and sclerosis of the liver; and 502(f) (1)—the labeling of the articles failed to bear adequate directions for use for the purposes for which they were intended, namely, (*Napier's 14 & 10 Vitamins-Minerals tablets*) in the treatment of arthritis, rheumatism, high blood pressure, improving eyesight, and insuring good health generally; (*Napier's Special Formula tablets*) for restoring lost manhood, improving

\*See also Nos. 6082-6084, 6088.

sexual powers and for sexual rejuvenation; (*Napier's Inhalant & Rubbing Oil*) for the treatment of sinus trouble, catarrh, asthma, hay fever, grippe, earache, chilblains, and pain in the neck, back, or leg; and (*Napier's Family Salve*) in the treatment of all kinds of burns, scalds, eczema, impetigo, skin rashes, poison oak, poison ivy, ringworm, itching, bleeding, blind or protruding hemorrhoids, and varicose vein sores.

PLEA: Not guilty.

DISPOSITION: The case came on for trial before the court and jury on 10-27-59.

On 10-29-59, the jury returned a verdict of guilty on counts 1, 3, 5, and 6, and not guilty on counts 2 and 4. On 12-17-59, the defendant was sentenced to 1 year imprisonment, which was suspended, and the defendant was placed on probation for 4 years.

6090. Bath minerals. (F.D.C. No. 43510. S. No. 51-468 P.)

QUANTITY: 30 3-lb. bags at Milwaukee, Wis.

SHIPPED: 5-14-59, from Soap Lake, Wash.

LABEL IN PART: (Sticker on bags) "Mother Nature Co. 'World's Most Miraculous Health Products' 1300 No. 12th St. \* \* \* Milwaukee, Wis." and (rubber stamp on bags) "H. H. Wolfgram, 1300 N. 12th Street, Milwaukee 5, Wis. Mother Nature Co."

ACCOMPANYING LABELING: Circulars entitled "Now You Can Take These Famous Mother Nature Baths."

RESULTS OF INVESTIGATION: The article was repacked and labeled by the dealer from bulk stock shipped as described above. The circulars were printed on order of the dealer.

LIBELED: 8-28-59, E. Dist. Wis.

CHARGE: 502(a)—while held for sale, the labeling which accompanied the article contained false and misleading representations that the article was an adequate and effective treatment for eliminating objectionable body odor; brightening the eyes; building up resistance to disease; inducing sound refreshing sleep; rheumatism; arthritis; neuritis; gout; high blood pressure; diabetes; gangrene; nervous disorders; circulatory ailments; general skin troubles; foot troubles, ulcers; Buerger's disease; skin infections; female disorders; varicose open sores; migrating phlebitis; osteomyelitis; and stomach and intestinal disorders; 502(b)(2)—the article failed to bear a label containing an accurate statement of the quantity of its contents; 502(e)(2)—the label of the article failed to bear the common or usual name of each of the active ingredients contained therein; and 502(f)(2)—the article was offered for vaginal douching and its labeling failed to bear a warning that it should not be used more than twice weekly unless otherwise directed by a physician.

DISPOSITION: 11-24-59. Default—destruction.

6091. Vydagen laxative compound. (F.D.C. No. 43530. S. No. 65-875 P.)

QUANTITY: 10 ctns., containing a total of 1,144 cans, at Hamburg, N.Y.

SHIPPED: 7-29-59, from Irvington, N.J.

LABEL IN PART: (Can) "(Vydagen A Supplementary Laxative Compound containing no Chemical or habit forming Drugs \* \* \* Ingredients: Agar Agar, Indian Plantago, Ovata Seed, Dextrine, Lactose \* \* \* Net Weight 5 Oz. Vydagen Products, 239 Munn Avenue, Irvington, N.J.)"



**LIBELED:** 9-10-59, W. Dist. N.Y.

**CHARGE:** 502(f) (1)—while held for sale, the labeling of the article failed to bear adequate directions for use for the prevention and treatment of headaches; coughs; irritability; nervousness; heartburn; indigestion; stomach trouble; neutralizing gas in the stomach; bed wetting; kidney ailments; for breaking up and eliminating poisons from the body, and restoring energy, pep, vitality, and good health; for removing parasites such as worms and tumors from the intestines; for enabling one to have a healthy body, healthy bowels, clean blood, better resistance to diseases and less sickness, and for enabling persons to eat better, feel better, and sleep better, which were the conditions and purposes for which the article was offered orally, on 8-17-59, by Maurice L. Harmelin, the owner of Vydagen Products, at the Erie County Fair, Hamburg, N.Y.

**DISPOSITION:** 10-14-59. Default—destruction.

**6092. Nutrin vitamin and mineral capsules.** (F.D.C. No. 43921. S. No. 66-601 P.)

**QUANTITY:** 7 pkgs., each containing 5 btls., and 20 pkgs., each containing 2 btls., at Pittsburgh, Pa.

**SHIPPED:** 10-19-59, from Waterloo, Iowa, by Vitarene Co.

**LABEL IN PART:** (Btl.) "Nutrin Multi-Vitamins & Minerals Each Capsule Contains: Vitamins \* \* \* Minerals \* \* \* 30 Capsules Distributed by Chester H. Nairne Co. 70 Tenth St. Niles, Ohio \* \* \* PL 75."

**ACCOMPANYING LABELING:** Leaflet in package entitled "Nutrin When Food Alone is not Enough Nutrin Capsules."

**RESULTS OF INVESTIGATION:** Mr. Chester H. Nairne had a sales booth on the premises of a retail store at Pittsburgh, Pa., from which he sold the article to the public, using an oral sales spiel and distributing the above-described leaflet.

**LIBELED:** 11-25-59, W. Dist. Pa.

**CHARGE:** 502(a)—when shipped and while held for sale, the labeling which accompanied the article contained false and misleading representations that it was adequate and effective for perfect health; active brain; steady nerves and happy disposition; strength, vigor, and unlimited energy; sturdy growth; good bones and teeth; regulation of nervous and muscular activity; coagulation of blood; proper functioning of the heart, muscles, nervous and body tissues; counteraction of acids; healing of wounds; strengthening of mental power; regulation of all the nutritive processes and prevention of goiter; purifying the system; and regenerating the body by purifying the blood; and that the food supplies generally available are nutritionally deficient and inferior, and that they lack sufficient amounts of the vitamins and minerals for normal nutrition; and 502(f) (1)—the labeling of the article failed to bear adequate directions for use in the treatment of underweight and overweight conditions; high blood pressure; reduced sexual powers; constipation; polio; improper sleep; diabetes; and colds, which were the conditions for which the article was offered in oral statements by Mr. Chester H. Nairne.

**DISPOSITION:** 12-17-59. Default—destruction.

**6093. Inhalant and rubbing oil.** (F.D.C. No. 43602. S. No. 71-111 P.)

**QUANTITY:** 20 8-oz. btls., 26 4-oz. btls., and 177 10-oz. btls., at Cincinnati, Ohio.



**SHIPPED:** The ingredients of the article consisting of oil of eucalyptus, peppermint oil, menthol, camphor, thymol, and coal tar colors were shipped from New York, N.Y., and St. Louis, Mo., between 8-17-59 and 9-24-59, and subsequently used in the manufacture of the article at Cincinnati, Ohio.

**LABEL IN PART:** "To-Ne-Ka \* \* \* Inhalant & Rubbing Oil."

**LIBELED:** 10-19-59, S. Dist. Ohio.

**CHARGE:** 502(f) (1)—while held for sale, the labeling of the article failed to bear adequate directions for use for the prevention and treatment of colds, bronchial coughs, croup, sore throat, sinus infections, tonsillitis, hay fever, asthma, arthritis, rheumatism, and all aches and pains to which the body is subject, which were the conditions and purposes for which Mrs. Jerry Smith Wirth orally offered the article during a demonstration on September 24, 1959, on the premises of a retail store at Cincinnati, Ohio.

**DISPOSITION:** 11-20-59. Default—destruction.

**6094. Allure (B-Former) cream and Fountain of Youth cream.** (F.D.C. No. 43600. S. Nos. 63-986/7 P.)

**QUANTITY:** 4 cases, each containing 144 unlabeled jars, and 86 unlabeled jars of *Allure (B-Former) cream*, and 62 unlabeled jars of *Fountain of Youth cream*, at Berlin, N.H., in possession of Starlite Products.

**SHIPPED:** Prior to January 1959, from New York, N.Y., by Tops Products Co.

**ACCOMPANYING LABELING:** (Loose labels) "Allure Cream Contains 20,000 E. H. Units Starlite Products \* \* \* Berlin, N.H. Contents 2 Oz. \* \* \* A Rich Hormone Cream"; "B-Former Cream Contains 20,000 Units E. H. A product of esthetic science for women who wish to improve their breasts. Contents 2 oz. RC Enterprises \* \* \* New York 10, N.Y."; "Fountain of Youth Wrinkleproof Cream 1 oz. Contains 7500 units E. H. & 100 Royal Jelly Starlite Products \* \* \* Berlin, N.H."; and leaflets entitled "Beauty Queen," "B-Former Method," and order forms.

**RESULTS OF INVESTIGATION:** The jars containing the articles were to be labeled in the normal course of the dealer's business operations, with the loose labels described above.

**LIBELED:** 10-16-59, Dist. N.H.

**CHARGE:** 502(a)—while held for sale, the labeling which accompanied the articles contained false and misleading representations that the "Beauty Queen" or "B-Former Method" would be an adequate and effective treatment for firming and enlarging the female breast and that the "Fountain of Youth Wrinkleproof Cream" contained the essential elements necessary in skin care and was adequate and effective in the treatment and prevention of wrinkles; 502(b)—when shipped, the articles failed to bear labels containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; 502(e) (2)—the labels of the articles, when shipped, failed to bear the common or usual name of each active ingredient; and 502(f) (1)—the labeling of the articles, when shipped and while held for sale, failed to bear adequate directions for use.

**DISPOSITION:** 12-7-59. Default—destruction.

**6095. Vitamin products.** (F.D.C. No. 43598. S. Nos. 43-935 P, 43-937/41 P, 56-817/9 P, 56-821/2 P.)

**QUANTITY:** 480 100-capsule btl. of *Merci-Caps*; 93 200-capsule btl. and 180 100-capsule btl. of *Fema-Formula*; 144 100-capsule btl. and 360 50-capsule

btls of *Vis-Vitae*; 156 100-tablet btls. and 348 50-tablet btls. of *M. O. F. #101 Vigorgy Tonik-Tabs*; 142 100-capsule btls. and 360 50-capsule btls. of *Calmettes*; and 82 100-capsule btls. and 180 50-capsule btls. of *Hipote Liv-Iron*; at Lexington (Red Bank), S.C., in possession of House of Nutritive Formulas.

SHIPPED: 10-22-58, from Long Island City, N.Y.

LABEL IN PART: "Capsules Merci-Caps \* \* \* Each Capsule contains: Salicylamide 4.4 Grains Caffeine 1.0 Grains Phenacetic 1.5 Grains Camphor Monobromated 1.0 Grains P. E. Belladonna 2/25 Grains \* \* \* Distributed by House of Nutritive Formulas 604 West Palmetto Street, Florence, S.C."; "14/263 Fema-Formula Capsules \* \* \* Distributed by House of Nutritive Formulas \* \* \* Each Fema-Formula Capsule contains: Ferrous Sulfate USP 3- $\frac{3}{8}$  gr. Whole Liver Dessicated 7 grs. Supplemented to contain approximately: Thiamine Chloride (B-1) 0.5 mg. Riboflavin (B-2) 1.0 mg. Nicotinamide 5 mg. Vitamin B-12 \* \* \* 1 mcgm. Folic Acid 0.05 mgm."; "53/163 Vis-Vitae (Vigor of Life) Capsules \* \* \* Distributed by House of Nutritive Formulas \* \* \* 604 West Palmetto Street, Florence, S.C. 31310 Each capsule contains: \* \* \* L-Lysine monohydrochloride 7.5 mgm. Vitamin A \* \* \* 12,500 USP Units \* \* \* Vitamin D \* \* \* 0 1000 USP Units \* \* \* Thiamin mononitrate (Vitamin B<sub>1</sub>) 5 mgm. \* \* \* Riboflavin (Vitamin B<sub>2</sub>) 5 mgm. \* \* \* Pyridoxine HCl (Vitamin B<sub>6</sub>) 1 mgm. \* \* \* Folic Acid 0.5 mgm. \* \* \* Ascorbic Acid 75 mgm. \* \* \* Niacinamide 40 mgm. \* \* \* Calcium Pantothenate 4 mgm. \* \* \* Vitamin B-12 (Cobalamin) 2 mcgm. \* \* \* Vitamin E (from D-Alpha tocopheryl acid Succinate) 21 U. \* \* \* Choline Bitartrate 31.4 mgm. \* \* \* Inositol 15 mgm. \* d-l Methionine 10 mgm. \* Calcium \* \* \* 75 mgm. \* \* \* Phosphorous \* \* \* 52 mgm. \* \* \* Cobalt \* \* \* 0.04 mgm. \* Iron \* \* \* 30 mgm. \* \* \* Copper \* \* \* 0.45 mgm. \* \* \* Magnesium \* \* \* 3 mgm. \* Molybdenum \* \* \* 0.1 mgm. \* \* \* Zinc \* \* \* 0.5 mgm. \* Iodine \* \* \* 0.1 mgm. \* \* \* Manganese \* \* \* 0.5 mgm. \* Potassium \* \* \* 2 mgm. \* Liver Whole Desiccated 50 mgm. \* \* \* \* Vitamin B-12 USP 1/100 USP Units Hesperidin purified 5 mgm. \* Rutin 2.5 mgm"; "M.O.F. #101 Vigorgy Tonik-Tabs (Formula for Men) \* \* \* Distributed by House of Nutritive Formulas \* \* \* 604 West Palmetto Street, Florence, S.C. 38812 Each tablet contains: Calcium Glycerophosphate 150 Mg. Tricalcium Phosphate 225 Mg. Ferric Hypophosphite 250 mg. Thiamin Chloride 15 mg. Vitamin B-12 (Cobalamin Conc.) 10 Mcg. Strychnine Sulfate 0.325 Mg."; "Calmettes \* \* \* Distributed by House of Nutritive Formulas \* \* \* 604 West Palmetto Street, Florence, S.C. 39566 Each \* \* \* Calmette Capsule contains: Thiamin HCl 10 mgm. Riboflavin 10 mgm. Niacinamide 100 mgm. Calcium Pantothenate 20 mgm. Pyridoxine HCl 2 mgm. Folic acid 1.5 mgm. Ascorbic acid 300 mgm. Vitamin B-12 (cobalamin conc.) 4 mcgm."; and "52/134 Hipote Liv-Iron Superhema Capsules The New Lease on Life Capsule Distributed by House of Nutritive Formulas \* \* \* 604 West Palmetto Street, Florence, S.C. 39606 Each capsule contains: Intrinsic Factor with Vitamin B-12  $\frac{1}{2}$  U.S.P. Unit Liver-stomach concentrate 175 mg. Vitamin B-12 Cobalamin Conc. 10 mcg. Folic Acid 1 mgm. Ferrous sulfate exsiccated 400 mgm. Ascorbic Acid 75 mgm."

ACCOMPANYING LABELING: Advertising mats headed "Are You A Once-A-Month Invalid?", "Your Health is Priceless," "For Your Good Health," "Get That 'Man Alive' Feeling," "Keep Calm With Calmettes," and "Add Life To Your Years."; catalogues reading in part "Winter-Spring 1958-59 \* \* \* Lexington,



S.C." and "Winter-Spring 1958-59 \* \* \* Lexington, S.C."; and leaflets on House of Nutritive Formulas letterhead beginning "Dear Friend."

LIBELED: 10-21-59, E. Dist. S.C.

CHARGE: 502(a)—while held for sale, the labeling which accompanied the articles contained false and misleading representations that the articles were an adequate and effective treatment (*Merci-Caps*) for migraine headache, bronchial asthma, and hayfever; (*Fema-Formula*) to build stronger blood; to produce good health; for painful menstruation, periodic cramps and irregularities; tired spells, tenseness, "periodic blues," nervousness, and depression; (*Vis-Vitae*) for premature aging; abnormal tiredness; mental strain and forgetfulness; digestive upsets; loss of appetite; susceptibility to colds and infection; run-down conditions; to produce vim, vigor and vitality and good health, and to stay well; (*Vigorgy Tonik-Tabs*) to produce energy, vigor and vitality; restore health, strength, manly vigor and sexual potency of men; (*Calmettes*) for nervous tension; stress conditions; physical and emotional upsets; upsets caused by business worry and over-indulgence; "jumpy feelings"; stress after serious injury such as burns; fracture of the long bones, and surgery; nervous breakdown; (*Hipote Liv-Iron*) for listless, pale, wan and worn, tired and run-down conditions; tired blood; loss of red blood cells; chills; shortness of breath; cold hands and feet; anemia; to restore healthy good looks, strength, and strong blood; to revitalize the entire system of the body and to pep up iron starved blood after colds, flu, or infections; and, in addition, the labeling accompanying the *Fema-Formula*, *Vis-Vitae*, *Vigorgy Tonik-Tabs*, *Calmettes*, and *Hipote Liv-Iron* and consisting of the "Vitamin-Data" chart appearing in the catalogue reading in part "Winter-Spring 1958-59 \* \* \* Florence, S.C." contained false and misleading representations that the *Fema-Formula*, *Vis-Vitae*, *Vigorgy Tonik-Tabs*, *Calmettes*, and *Hipote Liv-Iron* would be adequate and effective in the treatment and prevention of the diseases and symptoms listed in the chart under the headings "Functions" and "Deficiency Symptoms" and in producing the listed beneficial effects, namely, that the articles were adequate and effective in treating and preventing, low resistance to infection; retarded growth; loss of vigor; night blindness; loss of appetite; fatigue; neuritis; depression; nervous disorders; growth and digestive disturbances; skin disorders; nervous and intestinal disturbances; certain anemias; retarded growth in children; scurvy; tooth decay; hemorrhage; muscular weakness; rickets; bone deformities; failure of reproduction; and that the articles would aid growth and vitality necessary for reproduction; help prevent infection; aid appetite and digestion; help some forms of neuritis; stimulate body activity; induce normal cell growth and development; aid in prevention of pellagra; aid in prevention of skin and nervous disorders; help prevent certain anemias; promote growth; assist in proper formation of bones and teeth; prevent scurvy; help proper bone formation; aid in prevention of rickets; help to prevent sterility and muscular dystrophy; and

502(f) (2)—the labeling of the article of *Merci-Caps* failed to warn that a physician should be consulted if the article was to be taken by children under 12 years of age; that a physician should be consulted if the article was taken for arthritis or rheumatism and pain persisted for more than 10 days, or if redness occurred; that, because of its content of powdered extract of belladonna, the article should not be used by elderly persons unless directed by a physician; that the article should not be used by persons having glaucoma or excessive pressure within the eye unless directed by a physician; and its



labeling also failed to warn that the recommended dosage should not be exceeded and that the article was not for frequent or prolonged use.

DISPOSITION: 12-11-59. Default—destruction.

**6096. Niagara Thermo-Cyclopad and Hand Units.** (F.D.C. No. 43587. S. No. 52-640 P.)

QUANTITY: 10 cyclopad and 12 hand units at Minneapolis, Minn.

SHIPPED: Between 8-14-59 and 8-28-59, from Adamsville, Pa.

RESULTS OF INVESTIGATION: The Thermo-Cyclopad unit consisted of two separate parts: a cushioned pad containing an electric vibrating motor, and a heating element. The hand unit consisted of a vibrating electric motor within a lightweight tubular-shaped housing.

LIBELED: 10-13-59, Dist. Min.

CHARGE: 502(f) (1)—while held for sale, the labeling of the article failed to bear adequate directions for use as a treatment for relieving muscle spasms that surround the capillaries; relaxing spastic muscles through its penetrating action; improving circulation to allay aches and pains of all types of nervousness; relieving arthritis, bursitis, and rheumatism; for weight reducing, and to break down fatty cells in the body; giving health if used every day; and for use in polio centers and as hospital therapy equipment, which were the purposes and conditions for which the salesman, Clyde Dodd, orally offered the product at the Minnesota State Fair booth on 9-2-59.

DISPOSITION: 11-25-59. Default—delivered to the Food and Drug Administration.

#### DRUGS FOR VETERINARY USE

**6097. Scour Stop for Pigs.** (F.D.C. No. 43357. S. No. 62-815 P.)

QUANTITY: 108 8-oz. plastic btls. at Chicago, Ill.

SHIPPED: 2-2-59, from Kansas City, Mo., by Biolab.

LABEL IN PART: "Scour Stop For Pigs \* \* \* Animal Drug Products, Inc., Chicago, Illinois \* \* \* Each Fluid Ounce Contains: Phthalyl-sulfacetamide 6 gr. Sulfathiazole 6 gr. Kaolin 36 gr. Pectin 2.4 gr. Bismuth Subcarbonate 3 gr."

LIBELED: 8-24-59, N. Dist. Ill.

CHARGE: (502(a)—when shipped, the label statements "Scour Stop For Pigs" and "For Treatment of Both Infectious and Non-Infectious Diarrhea in baby pigs" were false and misleading since the article was not an adequate and effective treatment for such conditions and purposes; 502(b) (2)—the label of the article failed to bear a statement of the quantity of contents; and 502(f) (1)—the labeling of the article failed to bear adequate directions for use. (The directions borne on the label "Holding bottle upside-down press out one teaspoonful of Scour-Stop to judge the amount of pressure needed to give this amount. By putting nozzle in pig's mouth administer one teaspoonful for each five pounds body weight." were inadequate since it was impossible to follow such directions and accurately measure out the recommended dosage to be administered to the pigs.)

DISPOSITION: 9-22-59. Default—destruction.

**6098. Terephthalic acid.** (F.D.C. No. 43565. S. Nos. 53-963/4 P.)

**QUANTITY:** 47 cases, each containing 10 bags, and 6 cases, each containing 10 tins, at Springdale, Ark.

**SHIPPED:** Between 8-17-59 and 8-31-59, from Vineland, N.J., by Vineland Poultry Laboratories.

**LABEL IN PART:** (Bag) "Vineland Activator Solubilized Terephthalic Acid For Veterinary Use Only Caution: \* \* \* Net Contents 260 Grams [or tin "1½ lbs." ] Vineland Poultry Laboratories, Vineland, N.J. Los Angeles, Cal."

**RESULTS OF INVESTIGATION:** The article was not subject to exemption from the requirement that its label bear adequate directions for use since it was not delivered for use only in the manufacture of a new drug limited to investigational use. Instead the article was used in the preparation of poultry feed which was sold on a straight commercial basis for use by poultry raisers of the area.

**LIBELED:** 9-28-59, W. Dist. Ark.

**CHARGE:** 502(f) (1)—when shipped, the label of the article failed to bear adequate directions for use.

**DISPOSITION:** 12-12-59. Default—destruction.

**6099. Terephthalic acid (Dupont TPA).** (F.D.C. No. 43362. S. No. 57-127 P.)

**QUANTITY:** 11 75-lb. drums at Gainesville, Ga.

**SHIPPED:** 7-23-59 and 7-27-59, from Gibbstown, N.J., by E. I. du Pont de Nemours & Co.

**LABEL IN PART:** "DuPont TPA Terephthalic Acid Technical Grade \* \* \* E. I. du Pont de Nemours & Co. Inc. Wilmington 98, Delaware Caution: Manufacturing, Processing or Repacking in the preparation of a New Drug is limited by federal law to investigational use. An effective new drug application will be required before a product containing this material may be marketed."

**RESULTS OF INVESTIGATION:** Investigation showed that the article was to be used in the preparation of poultry feed which was sold on a straight commercial basis for use by poultry raisers; and therefore the article was not subject to the exemption afforded by the regulations from bearing adequate directions for use since the delivery was not made for use only in the manufacture of a new drug limited to investigational use.

**LIBELED:** 8-25-59, N. Dist. Ga.

**CHARGE:** 502(f) (1)—when shipped, the labeling of the article failed to bear adequate directions for use.

**DISPOSITION:** 10-16-59. Default—destruction.

## **DRUGS AND DEVICE ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS**

### **DRUGS FOR HUMAN USE**

**6100. Terpin hydrate.** (F.D.C. No. 43797. S. No. 77-928 P.)

**QUANTITY:** 2 25-lb. drums at Detroit, Mich.

**SHIPPED:** 4-1-59, from Philadelphia, Pa., by Physicians Drug & Supply Co.

**LABEL IN PART:** "C29816 Physicians Drug & Supply Co. \* \* \* Philadelphia 6 Pa. \* \* \* No. 9680 D. 74 Terpin Hydrate N.F. \* \* \* 5.335."

RESULTS OF INVESTIGATION: Analysis showed that the article failed to comply with the National Formulary specifications for *terpin hydrate* in that it had an odor not permitted by the National Formulary.

LIBELED: 11-10-59, E. Dist. Mich.

CHARGE: 501(b)—when shipped, the quality and purity of the article fell below the standard for *terpin hydrate* set forth in the National Formulary.

DISPOSITION: 12-7-59. Default—destruction.

6101. Contact lens wetting solution. (F.D.C. No. 43914. S. No. 70-347 P.)

QUANTITY: 236 btls. at Philadelphia, Pa.

SHIPPED: 8-4-59, from Wauconda, Ill., by Micon Laboratories.

LABEL IN PART: "5 cc. Sample Mi-Con Wetting Solution \* \* \* Micon Laboratories, 905 Jackson Street, Wauconda, Ill.

LIBELED: 11-13-59, E. Dist. Pa.

CHARGE: 501(c)—when shipped, the purity and quality of the article fell below that which it purported or was represented to possess since it purported to be suitable for use in the eye and for cleaning contact lenses, whereas, it was not suitable for such uses and purposes because it was contaminated with large numbers of viable micro-organisms.

DISPOSITION: 12-16-59. Default—destruction.

6102. Obes-Ebb tablets and thyroid tablets. (F.D.C. No. 43330. S. Nos. 52-887 P, 52-891 P, 53-565/6 P.)

QUANTITY: 491 1,000-tablet btls. of *Obes-Ebb tablets* and 8 1,000-tablet btls. of *thyroid tablets* at Los Angeles, Calif.

SHIPPED: 3-17-59 and 3-31-59, from Hoboken, N.J., by General Pharmacal Co., Inc.

LABEL IN PART: "Green No. 1 Obes-Ebb \* \* \* Amphetamine Sulfate 10 Mgm. Thyroid 1 Gr., Aloin  $\frac{1}{4}$  Gr. Atropine Sulfate 1/360 Gr. \* \* \* General Pharmacal Co. Hoboken, New Jersey \* \* \* 2619"; "Yellow No. 2 Obes-Ebb \* \* \* Thyroid 1 Gr., \* \* \* 2635"; "Brown No. 3 Obes-Ebb, Each Tablet Contains: Phenobarbital  $\frac{1}{4}$  Grain \* \* \* Thyroid 1 Grain \* \* \* 2636"; "FHJ Tablets Thyroid \* \* \* Contains 2 Grain Thyroid Powder USP \* \* \* F. H. J. Laboratories, Inc., New York, N.Y. Control 2637."

RESULTS OF INVESTIGATION: Examination showed that the articles (all lots) contained less than the labeled amounts of thyroid.

LIBELED: 8-4-59, S. Dist. Calif.

CHARGE: 501(b)—when shipped, the strength of the *thyroid tablets* differed from, and their quality fell below, the standard for *thyroid tablets* set forth in the United States Pharmacopeia; 501(c)—the strength of the *Obes-Ebb tablets* differed from that which they purported and were represented to possess; and 502(a)—the label statements (*Obes-Ebb tablets*) "Each Tablet Contains Thyroid 1 Gr." and (*thyroid tablets*) "Contains 2 Grain Thyroid Powder USP" were false and misleading.

DISPOSITION: 8-26-59. Default—destruction.

6103. Li-Folic-B<sub>12</sub>. (F.D.C. No. 43415. S. No. 76-043 P.)

QUANTITY: 273 vials at St. Louis, Mo.

SHIPPED: 3-9-59, from Dayton, Ohio, by Durr Products, Inc.



**LABEL IN PART:** "10 cc \* \* \* Li-Folic-B-12 Each cc Contains: Sodium Folate 10 Mgs. Vitamin B-12 USP 100 Mcgms. Niacinamide 75 Mgs. and Benzyl Alcohol 1.5% Dissolved in Liver Injection USP Equivalent in Vitamin B-12 Activity to 20 Mcgms. of Cyanocobalamin Per cc \* \* \* Distributed by Storck Pharmaceuticals St. Louis 10, Mo."

**RESULTS OF INVESTIGATION:** Analysis showed that the article contained approximately 75 percent of the declared amount of vitamin B<sub>12</sub>.

**LIBELED:** 8-3-59, E. Dist. Mo.

**CHARGE:** 501(c)—when shipped, the strength of the article differed from that which it purported and was represented to possess, namely, vitamin B<sub>12</sub> activity per cubic centimeter equivalent to 20 micrograms of cyanocobalamin.

**DISPOSITION:** 9-10-59. Default—destruction.

**6104. Femone tablets.** (F.D.C. No. 43433. S. No. 60-868 P.)

**QUANTITY:** 16 btls. at Cleveland, Ohio.

**SHIPPED:** 6-30-58, from Madison Heights, Mich., by Chem-Tek, Inc.

**LABEL IN PART:** "Femone S. C. Yellow Conjugated Estrogens 1.25 mg. 1000 contents CT 835 tablets each tablet contains: Naturally occurring water soluble conjugated estrogens equivalent in biological activity to 1.25 Mg. Sodium Estrone Sulfate Distributed by the T. J. Brown Company, Cleveland, Ohio."

**RESULTS OF INVESTIGATION:** Examination showed that the total estrogen content per tablet corresponded to not more than 0.79 milligram of sodium estrone sulfate.

**LIBELED:** 9-2-59, N. Dist. Ohio.

**CHARGE:** 501(c)—when shipped, the strength of the article differed from that which it purported and was represented to possess.

**DISPOSITION:** 10-8-59. Default—destruction.

**6105. Prophylactics.** (F.D.C. No. 43781. S. No. 22-508 P.)

**QUANTITY:** 224 ctns., each containing 12 boxes of 12 units each, at Omaha, Nebr., in possession of Dean Rubber Co.

**SHIPPED:** 9-30-59, from North Kansas City, Mo., by Dean Rubber Co.

**LABEL IN PART:** "Peacocks The Original Reservoir Ends \* \* \* Product of Dean Rubber Mfg. Co., N. Kansas City, Mo."

**RESULTS OF INVESTIGATION:** Examination showed that 1.0 percent of the article was defective in that it contained holes.

**LIBELED:** 10-27-59, Dist. Nebr.

**CHARGE:** 501(c)—when shipped and while held for sale, the quality of the article fell below that which it purported to possess.

**DISPOSITION:** 12-15-59. Consent—claimed by Dean Rubber Mfg. Co., Omaha, Nebr. Segregated; 23,439 units were found free of holes.

**DRUG FOR VETERINARY USE**

**6106. Sulfodene Medication.** (F.D.C. No. 43437. S. No. 48-991 P.)

**QUANTITY:** 425 cases, 36 4-oz. btls. each, 2 cases, 24 1-pt. btls. each, and 1 1-gal. btl., at San Francisco, Calif.

**SHIPPED:** 5-13-59, from Chicago, Ill., by Jerome & Co.

**LABEL IN PART:** (Btl.) "Dr. Merricks Sulfodene Medication scientific formulation for itching, scratching dogs, cats. \* \* \* A Div. of Eastco, Inc., White Plains, N.Y. Dist. Active Ingred. 2-Mercaptobenzothiazole 1½ percent."

**RESULTS OF INVESTIGATION:** Analysis showed that the article contained materially less than the declared amount of 2-Mercaptobenzothiazole and that it contained about .24 percent of undeclared hexachlorophene.

**LIBELED:** 8-27-59, N. Dist. Calif.

**CHARGE:** 501(c)—when shipped, the strength of the article differed from that which it purported and was represented to possess; 502(a)—the label statement "Active Ingred. 2-Mercaptobenzothiazole 1½ percent" was false and misleading; and 502(e) (2)—the label failed to bear the common or usual name of the active ingredient, hexachlorophene.

**DISPOSITION:** 10-5-59. Default—destruction.

### DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS\*

**6107. Weight-away tablets.** (F.D.C. No. 43586. S. No. 7-317 P.)

**QUANTITY:** 383 62-tablet btls. at New Haven, Conn.

**SHIPPED:** 8-10-59 and 8-14-59, from West Springfield, Mass., by Slendora Salons, Inc.

**LABEL IN PART:** "92085 Weight-Away \* \* \* Distributed by Weight Away Sales Co., West Springfield, Mass. Each tablet contains Phenylpropanolamine Hydrochloride 25 Mg."

**ACCOMPANYING LABELING:** Display cards and posters reading in part "Take Weight-Away with Just 3-A-Day \* \* \* Weight-Away Sales Co."

**LIBELED:** 10-12-59, Dist. Conn.

**CHARGE:** 502(a)—when shipped, the name and the labeling of the article contained false and misleading representations that the article was an adequate and effective appetite suppressant and would cause one to lose weight without dieting.

**DISPOSITION:** 2-5-60. Default—destruction.

**6108. Dex-A-Diet tablets.** (F.D.C. No. 44029. S. No. 91-504 P.)

**QUANTITY:** 22 21-tablet btls. and 9 100-tablet btls. at Denver, Colo.

**SHIPPED:** 6-15-59, from Detroit, Mich., by Alpha Tablets Co.

**LABEL IN PART:** "Dex-A-Diet A True Appetite Depressant Packaged by O'Conner Bros. Drug Co. For Alpha Tablets Co. Detroit, Michigan \* \* \* Each Tablet Contains: Phenylpropanolamine Hydrochloride 25 mg."

**LIBELED:** 1-12-60, Dist. Colo.

**CHARGE:** 502(a)—when shipped, the label of the article contained false and misleading representations that the article was adequate and effective as an appetite depressant and in the management and treatment of obesity.

**DISPOSITION:** 2-16-60. Default—destruction.

**6109. Phylorinol.** (F.D.C. No. 44242. S. No. 62-541 P.)

**QUANTITY:** 174 individually cartoned btls. at Chicago, Ill.

\*See also Nos. 6081, 6083-6085, 6087, 6089, 6090, 6092, 6094, 6095, 6097, 6102, 6106.

SHIPPED: 1-8-60, from Montrose, Calif., by Schaffer Laboratories.

LABEL IN PART: (Ctn. and btl.) "Phylorinol (Fill-Or-Inol) For Oral Care A scientific combination of Iodophenol, Chlorophyl and Boric Acid \* \* \* Directions For the Dentist \* \* \* Home Use \* \* \* Net Contents 8 Fl. Oz. \* \* \* Schaffer Laboratories, 3712-A Park Place, Montrose, California."

ACCOMPANYING LABELING: Folder in carton entitled "For Phylorinol Oral Care" and leaflet in carton entitled "Directions For Use to Patient."

LIBELED: 2-15-60, N. Dist. Ill.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for control of infections in the oral cavity; tooth sensitivity caused by receding gums; peridental pockets; pericoronitis; surgical care; immediate dentures; denture soreness; dry sockets; Vincent's infection; gingivitis; pregnancy stomatitis; inflamed or bleeding gums; and canker sores.

DISPOSITION: 3-15-60. Default—destruction.

**6110. Vegetrates lecithin with vitamin D. (F.D.C. No. 43941. S. Nos. 52-958/9 P.)**

QUANTITY: 23 cases, 48 100-capsule btl. each, 7 cases, 48 60-capsule btl. each, 1 case of 24 60-capsule btl., 5 cases, 48 250-capsule btl. each, 6 cases, 24 250-capsule btl. each, 3 cases, 24 500-capsule btl. each, 8 cases, 12 500-capsule btl. each and 17 1,000-capsule btl., 32 bulk ctn., 15,000 capsules each, 1 bulk ctn. of 16,500 capsules, and 1 bulk ctn. of 13,800 capsules, at Los Angeles, Calif., in possession of Vegetrates Co.

SHIPPED: 6-22-59 and 9-22-59, from Detroit, Mich.

LABEL IN PART: (Btl.) "Vegetrates Lecithin with Vitamin D Each soluble gelatin capsule contains: Soya Lecithin 259.20 mg. Soybean Oil 111.00 mg. Vitamin D 150 U.S.P. Units (from Irradiated Ergosterol)—Dist. by Vegetrates Co., Los Angeles, Calif."

ACCOMPANYING LABELING: Leaflets reading in part "Your Heart \* \* \* Your Brain \* \* \* Your Nerves \* \* \* All Contain Lecithin."

RESULTS OF INVESTIGATION: The article in the bottles was repacked and re-labeled from bulk cartons shipped as described above.

The leaflets were printed locally at the request of the dealer.

LIBELED: 12-7-59, S. Dist. Calif.

CHARGE: 502(a)—while held for sale, the labeling which accompanied the article contained false and misleading representations that the article was an adequate and effective treatment for diseases of the heart, brain, and nerves; that it would prevent and remove fatty deposits from the blood stream; that it served an essential function in the bile to keep cholesterol in solution; that it would control fats in the liver; that it was an adequate and effective treatment for nervousness, fatigue, emotional irritability, headaches, insomnia, and many other symptoms; and that lecithin, one of the ingredients in the product, was an essential nutrient which must be present in the diet.

DISPOSITION: 3-15-60. Default—destruction.

**6111. Cos-Mel Honey. (F.D.C. No. 44225. S. No. 85-918 P.)**

QUANTITY: 5 cases, each containing 12 3-oz. cartoned jars, at New York, N.Y., in possession of John S. Nairn.



**SHIPPED:** Some time in January 1960, by John S. Nairn, from his bee farm in Somerville, N.J., where the honey is produced, packed, and labeled by Mr. Nairn.

**LABEL IN PART:** (Ctn. and jar) "Cos-Mel Honey A Product of Bees Makers of Royal Jelly John S. Nairn, \* \* \* New York 6, N.Y."

**ACCOMPANYING LABELING:** Booklet entitled "How Does the Busy Little Bee"; letters signed "Joseph E."; letter headed "Cincinnati 20, Ohio"; testimonial letter dated "December 29th/59" signed "T.H."; price list; booklet entitled "Testimonials From Users of Cos-Mel"; and a sheet of paper bearing the words "Liquid Open with Care."

**RESULTS OF INVESTIGATION:** The above-mentioned booklets were printed in New York and the other accompanying labeling was printed in New Jersey, for or on the behalf of the distributor.

**LIBELED:** 2-16-60, S. Dist. N.Y.

**CHARGE:** 502(a)—when shipped and while held for sale, the labeling of the article contained false and misleading representations that the article was adequate and effective for the prevention and treatment of arthritis; asthma; cancer; Hodgkin's disease; colds; coughs; diabetes; glaucoma; shingles; sore throat; stomach and intestinal ailments; skin burns; that it would restore eyesight; help create immunity and resistance to disease; and help balance the electrical energy of the body; that it would maintain and restore youth and good health, regain energy, and strength; and that it would relieve pain and nervous strain.

**DISPOSITION:** 3-22-60. Default—destruction.

**6112. Tracy Body-Tone liniment.** (F.D.C. No. 44026. S. No. 77-758 P.)

**QUANTITY:** 34 6-oz. btl., 91 pt. btl., and 13 1-gal. btl., at Detroit, Mich., in possession of Woodard Laboratories.

**SHIPPED:** 2-27-59, from Bryan, Ohio.

**LABEL IN PART:** (Btl.) "Tracy Body-Tone Liniment \* \* \* Active Ingredients Methyl Salicylate (Synthetic), Camphor, Witch Hazel and Menthol (Racemic), Isopropyl Alcohol 54% \* \* \* Distributed by Tracy's Professional Service, 408 Fox Bldg., Detroit 1, Mich."

**ACCOMPANYING LABELING:** Folders entitled "Tracy's Body-Tone Therapy Book."

**LIBELED:** 1-18-60, E. Dist. Mich.

**CHARGE:** 502(a)—while held for sale, the labeling which accompanied the article contained false and misleading representations that the article was an adequate and effective treatment for sprains; sciatica; arthritis pains in joints; swollen feet and ankles; head colds; headaches; sinus trouble; fainting spells; varicose veins; and spot reducing.

**DISPOSITION:** 3-4-60. Consent—claimed by Tracy's Professional Service, Detroit, Mich., and relabeled.

**6113. Beautycare capsules.** (F.D.C. No. 44149. S. No. 17-927 P.)

**QUANTITY:** 8 cases, each containing 24 100-capsule btl., and 5 cases, each containing 24 unlabeled 100-capsule btl., at Nashville, Tenn., in possession of Parthenon Pharmaceuticals, Inc.

**SHIPPED:** 8-4-59, from Auburn, Mass., by Cowley Pharmaceuticals, Inc.

**LABEL IN PART:** "Ten Grain Gelatin Caps BEAUTYCARE No Fat Gelatin Caps a food supplement for Lovely Nails & Hair A pure high protein sugarless gelatin Containing Natural Protein, Peptides, and Amino Acids \* \* \* Distributed by Parthenon Pharmaceuticals, Inc., Nashville 8, Tennessee."

**ACCOMPANYING LABELING:** Leaflets entitled "Beautycare Gelatin" and loose "Beautycare" bottle labels.

**RESULTS OF INVESTIGATION:** The leaflets and the loose "Beautycare" labels were printed in Nashville at the dealer's request. The leaflets were attached to each bottle with a rubber band by the dealer. The labels were shipped by the dealer to Auburn, N.J., where they were to be affixed to each bottle by Cowley Pharmaceuticals, Inc.

**LIBELED:** 12-29-59, M. Dist. Tenn.

**CHARGE:** 502(a)—when shipped and while held for sale, the labeling of the article contained false and misleading representations that the article would produce more manageable and lustrous hair; more beautiful hair and skin; curb the appetite; help build blood; aid in losing weight; and that it contained the essential amino acid necessary for tissue growth.

**DISPOSITION:** 4-5-60. Default—destruction.

**6114. Vitamin capsules.** (F.D.C. No. 42757. S. Nos. 13-790/5 P.)

**QUANTITY:** 2 ctns., each containing 6,000 capsules in pliofilm bags, of *Darwins Therapeutic Vitamin B Complex*, 48 100-capsule btls, of *Magnum Therapeutic Vitamin B Complex*, 34 100-capsule btls. of *Therapeutic Vitamin B Complex*, 47 100-capsule btls. of *Bioflac*, 3,000 capsules of *Kolisin* in bulk container, 36 100-capsule btls. of *Lipo-In*, 300 capsules of *Utrapacs*, 21 100-capsule btls. of *X-Tra-Hi*, and 36 100-capsule btls. of *Lecithin and Vitamin D*, at Birmingham, Mich., in possession of Vitamin Center.

**SHIPPED:** The vitamin D in the *Lecithin and Vitamin D* capsules had been purchased from a firm in Chicago, Ill., and used in the manufacture of such capsules at Detroit, Mich. The finished *Lecithin and Vitamin D* capsules were shipped on 9-2-58 to the dealer, from Detroit, Mich., and the other articles were shipped to the dealer between 8-12-58 and 10-6-58, from Buffalo, N.Y., and Baudette, Minn.

**LABEL IN PART:** (Ctn.) "Darwins Therapeutic Vitamin B Complex Fortified with Liver, Iron, Folic Acid, Vitamin C and B<sub>12</sub>"; (btl.) "Magnum Therapeutic Vitamin B Complex Fortified with Liver, Iron, Folic Acid, Vitamin C and B<sub>12</sub> Vitamin Center Distributors, Detroit 31, Michigan 1410"; "Therapeutic Vitamin B Complex A Special Formula Fortified with Liver, Iron, Folic Acid, Vitamin C, Choline, Inositol and B<sub>12</sub> \* \* \* 1411"; "Bioflac Each capsule contains: 100 Mg. Citrus Bioflavonoids Complex from Lemons, 100 Mg. Vitamin C \* \* \* 1484"; (bulk container and btl.) "Kolisin [or "Lipo-In"] \* \* \* Each capsule contains: Choline Bitartrate 250 Mg. Inositol 250 Mg. dl-Methionine 150 mg."; (bulk container) "Utrapacs Each capsule contains: Vitamin A 30,000 USP Units Vitamin D 2,500 USP Units Vitamin B<sub>1</sub> (Thiamine Chloride) 10 mg. Vitamin B<sub>2</sub> (G) Riboflavin 10.0 mg. Vitamin B<sub>6</sub> 0.5 mg. Niacinamide 150.0 mg. B<sub>12</sub> \* \* \* 5 mcg. Vitamin C (ascorbic Acid) 3000 USP Units Folic Acid 0.25 mg. Calc. Pantothenate 10 mg. Choline Citrate 10.0 mg. Inositol 10.0 mg. dl-Methionine 10.0 mg. Vitamin E 5.0 mg."; (btl.) "X-Tra-Hi Geriatric-Therapeutic Fortified with Vitamins A, D, C, B<sub>12</sub> and Niacinamide \* \* \* 1431 & 1432," and "Lecithin Capsules \* \* \*



Each capsule contains: 4 grains Lecithin and 150 USP Units Vitamin D suspended in 3 minims pure Soybean Oil \* \* \* 1421."

ACCOMPANYING LABELING: Catalog entitled "Don't Shut Your Eyes"; folders entitled "Quality Vitamins" and "Magnums Over 57 Pounds"; and leaflets entitled "Read What Buyers Say," "It's Fine For You," and "Do You Feel Your Age Creeping Up On You?"

RESULTS OF INVESTIGATION: The articles in the 100-capsule bottles were re-packed and relabeled from bulk stock shipped as described above.

The catalog, folders and leaflets were all prepared by the dealer.

LIBLED: 1-9-59, E. Dist. Mich.

CHARGE: 502(a)—while held for sale, the labeling which accompanied the articles contained false and misleading representations that the *Darwins Therapeutic Vitamin B Complex* and *Magnum Therapeutic Vitamin B Complex* would be an adequate and effective treatment for regulating the many chemical processes of the body to correct or prevent faulty hearing; cataract of the eye; heart trouble; arthritis; rheumatism; hardening of the arteries; diabetes; formation of gallstones; nervous disorders; and indigestion or constipation; that the remainder of the articles would be an adequate and effective treatment for hardening of the arteries; defective hearing; kidney stones; gallstones; colds; influenza; tonsilitis; respiratory infection; arthritis and rheumatic disorders; habitual abortions and miscarriages; thrombosis; hemorrhages; diabetes; high blood pressure; geriatric conditions; cirrhosis of the liver; cysts; sinus and bronchial infections; acne; and psoriasis; and that all the articles contained false and misleading representations that vitamin deficiency was almost universal, thus necessitating supplementation of the diet with this type of vitamin preparation, and that the articles were an adequate and effective treatment for increasing the life span, deferring senility, preventing cancer, and preventing circulatory disorders.

DISPOSITION: Frank Mellinger, Detroit, Mich., appeared as claimant. On 3-4-60, the claimant having consented, without admitting that the literature complained of was in violation of the law, a decree was entered ordering (a) that the accompanying literature be destroyed; (b) that the claimant no longer use the literature as labeling for the articles, or any other labeling which represents that the articles are adequate and effective treatment for the diseases, symptoms, and conditions described in the libel; and (c) that the claimant shall not dispose of the articles contrary to the provisions of the law.

6115. Beautiaire massage pillow. (F.D.C. No. 44021. S. No. 93-166 P.)

QUANTITY: 36 individually cartoned pillows at Boise, Idaho.

SHIPPED: 10-15-59, from New York, N.Y., by Morris Struhl, Inc.

LABEL IN PART: (Ctn.) "Beautiaire Massage Pillow the all purpose vibrating pillow \* \* \* Morris Struhl, Inc., New York 10, New York."

ACCOMPANYING LABELING: Leaflet in carton entitled "How to enjoy \* \* \* Beautiaire Electric Massage Pillow."

RESULTS OF INVESTIGATION: Examination showed the article to be a cloth-covered pillow containing an electric motor capable of providing vibrations.

LIBLED: 1-4-60, Dist. Idaho.

CHARGE: 502(a)—the labeling of the article, when shipped, contained false and misleading representations that the article was an adequate and effective treatment for easing nervous tensions; firming flabby flesh; melting away fatty



tissues; aiding in reducing; stimulating and increasing blood circulation; and soothing away aches and pains.

DISPOSITION: 1-28-60. Default—destruction.

**6116. Flex-O-Matic massage cushion.** (F.D.C. No. 43780. S. No. 27-284 P.)

QUANTITY: 7 individually cartoned devices, at Pardeeville, Wis.

SHIPPED: 8-31-59, from Minneapolis, Minn., by Health Products, Inc.

LABEL IN PART: (Device) "Flex-O-Matic Health Products Inc. \* \* \* Minneapolis 5, Minnesota."

ACCOMPANYING LABELING: Leaflets entitled "New Method Helps Bring Sleep" and booklets entitled "Presenting the New Flex-O-Matic Electronic Massage Cushion."

RESULTS OF INVESTIGATION: The article was a pad about two feet long by one foot wide consisting of a metal frame covered with foam rubber. Attached to one end of the pad was a foam rubber-covered metal tube containing an electric vibrating motor. A heating element was contained within the pad. A separate cabinet allowed for regulation of vibratory action and amount of heat.

LIBELED: 11-9-59, W. Dist. Wis.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for easing tension and aches and pains; inducing sleep; controlling posture; increasing circulation; relieving arthritis, bursitis, lumbago, fibrositis and back pain; and reducing weight.

DISPOSITION: 2-25-60. Default—delivered to the Food and Drug Administration.

**6117. Slenderoll device.** (F.D.C. No. 44055. S. No. 62-116 P.)

QUANTITY: 29 devices at San Francisco, Calif.

SHIPPED: 10-7-58, from Northvale, N.J., by Profile Slenderizing Salons.

LABEL IN PART: "Slenderoll Model No. 161 Profile Slenderizing Salons, Northvale, N.J."

ACCOMPANYING LABELING: Circular in carton entitled "Getting the Most from your Profile Slenderoll."

LIBELED: 2-8-60, N. Dist. Calif.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for removing excess inches, weight, stimulating circulation; toning the tissues and muscles; reducing flabbiness; relieving aches and pains; slenderizing; rolling away ugly fat; spot reducing and achieving a slimmer figure.

DISPOSITION: 3-24-60. Default—a number of the devices were delivered to the Food and Drug Administration and the remainder were destroyed.

**6118. Swedish Masseur Contour Vibrator.** (F.D.C. No. 43325. S. No. 52-113 P.)

QUANTITY: 16 individually cartoned devices at Fargo, N. Dak., in possession of O. J. deLendrecie Co.

SHIPPED: 3-3-59, from Newark, N.J., by Remington Sales.

LABEL IN PART: (Ctn.) "Relax Revitalize Professional Swedish Masseur De-Luxe \* \* \* Salon Vibration in Home Privacy \* \* \* A Product of Remington Research Inc.," (tag) "UL Professional Contour Vibrator."

**ACCOMPANYING LABELING:** Proof copy of newspaper advertisement and newspaper advertisement used in placard, reading in part "Spot reduce \* \* \* Swedish Masseur."

**RESULTS OF INVESTIGATION:** The article was a padded and upholstered device, 5" by 5" by 12" in size, contour-shaped on one side to fit the curvatures of the body. It contained a small electric motor capable of providing vibration.

**LIBELED:** 7-29-59, Dist. N. Dak.

**CHARGE:** 502(a)—when shipped and while held for sale, the name of the article and the labeling which accompanied it contained false and misleading representations that the article was an adequate and effective treatment for reducing; slenderizing; reportioning the entire body; removing excess fatty deposits; tightening and toning muscle tissues and sagging skin; restoring the body to youthful tonicity and vibrancy of the "18 year old" midriff; relieved nervousness and tension, and circulation, banished backaches and rheumatic pains and promoted sleep.

**DISPOSITION:** 3-21-60. Consent—claimed by Remington Research, Inc., New York, N.Y., and relabeled.

**6119. Electro-Galvanic Bracelets.** (F.D.C. No. 42876. S. No. 24-857 P.)

**QUANTITY:** 130 individually cartoned bracelets at Detroit Lakes, Minn., in possession of Clinton Elijah, and 46 individually cartoned bracelets in possession of Glenn W. Tostenrud, t/a Nome Distributing Co.

**SHIPPED:** 1-9-59 and 1-15-59, from Lakewood, N.J., by Lev P. Sukacev (Natural Plating Corp.), to Clinton Elijah who subsequently delivered a number of the devices to Mr. Tostenrud.

**LABEL IN PART:** (Device) "Electro Therapeutic Bracelet" and (ctn.) "Electro-Galvanic Bracelet New!"

**ACCOMPANYING LABELING:** Leaflet in carton entitled "The Electro-Galvanic Bracelet \* \* \* Local Representative Distributed by Nome Distributing Company, Detroit Lakes, Minnesota."

**RESULTS OF INVESTIGATION:** The article was a white metal wrist bracelet. A clear plastic plate with imbedded loops of wire was attached under the "name plate," and a clear plastic piece was also attached under the "catch" links of the bracelet.

The leaflets were printed on order of the dealer and were placed in the cartons by the dealer.

**LIBELED:** 3-10-59, Dist. Minn.

**CHARGE:** 502(a)—when shipped and while held for sale, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for relieving body aches and pains, sciatica, arthritis, bursitis, neuritis, contusions, sprains, dislocations, sinusitis, muscle inflammation; that the article may be contraindicated and should be used discriminately and with caution in such conditions as stomach ulcer, pulmonary tuberculosis, nerve injuries, malignancies, and in pregnancy; that the therapeutic value of the article had been established in experiments made by the Nanterre Hospital, France; and that the article was an "Electro-Therapeutic Bracelet"; and 502(b) (1)—the label failed to bear the name and place of business of the manufacturer, packer, or distributor.



**DISPOSITION:** 4-25-60 and 4-27-60. Clinton Elijah, claimant, having answered the Government's interrogatories and later consented to the entry of a decree, judgment of condemnation was entered and the court ordered that 36 bracelets and leaflets be delivered to the Food and Drug Administration and that the remainder of the articles be destroyed.

**6120. Unassembled color lamp units.** (F.D.C. No. 43324. S. No. 53-109 P.)

**QUANTITY:** 5 unassembled units consisting of lamp bases and colored plastic slides at Arlington, Calif., in possession of Stanley A. Burroughs, t/a Burroughville Specialties.

**SHIPPED:** (Lamp bases) During February 1959, from Brooklyn, N.Y., and (color slides) during May 1959, from New York, N.Y.

**LABEL IN PART:** (Lamp base) "Inspected Portable Lamp Issue No. 20,994."

**ACCOMPANYING LABELING:** Books entitled "Living Creatively through Vita-Flex, Color Vibration and Nutrition" and booklets entitled "Master Cleanser."

**RESULTS OF INVESTIGATION:** Examination showed that the lamp base was a spring-clamp portable unit with adjustable socket, porcelain keyless mechanism, cord and plug.

The slides were of colored plastic cut 7" by 8" and were in sets of five colors, red, yellow (orange), green, blue, and violet (dark blue).

**LIBELED:** 8-6-59, S. Dist. Calif.

**CHARGE:** 502(a)—While held for sale, the labeling which accompanied the article contained false and misleading representations that the article was a necessary adjunct to the adequate and effective treatment of boils; abscesses; carbuncles; eczema; all types of weeping or dry sores anywhere on the body; cancer; leukemia; tumors; varicose veins; hemorrhoids; glaucoma; phlebitis; colds; influenza; virus X; measles; whooping cough; scarlet fever; pneumonia; bronchial disorders; all diseases of the eyes, nose and throat; arthritis; rheumatism; bursitis; neuritis; constipation; anemia (all kinds); asthma; hay fever; sinusitis; tuberculosis and all other diseases which may effect the body of man.

**DISPOSITION:** On 8-24-59, Stanley A. Burroughs, claimant, filed an answer denying that the article was misbranded, and in addition filed a counter claim for damages against the Government. On 9-11-59, the Government filed a motion to strike portions of claimants answer, including claimants counter claim. On 12-18-59, the claimant filed an amended answer.

On 1-4-60, the Government's motion to strike was granted. On 2-1-60, the Government served written interrogatories upon the claimant, and filed requests for admissions with the court. Thereafter, upon consent of the claimant, the claimant's answer was withdrawn, and a default decree was entered ordering the article delivered to the Food and Drug Administration.

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Merci-Caps capsules.....	6095	6095, 6103, 6114	
Napier's Family Salve.....	<sup>1</sup> 6089	Weight-away tablets.....	6107
14 & 10 Vitamins-Minerals		Worm remedy.....	6086
tablets .....	<sup>1</sup> 6089	X-Tra-Hi capsules.....	6114

## SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

	N.J. No.		N.J. No.
Allure, Inc.:		Allure Salon:	
Allure bust development de-		Allure bust development de-	
vice.....	6082-6084	vice.....	6083

<sup>1</sup>(6089, 6120) Prosecution contested.

	N.J. No.		N.J. No.
Alpha Tablets Co.:		Jerome & Co.:	
Dex-A-Diet tablets-----	6108	Sulfodene Medication (veteri- nary) -----	6106
Biolab:		Micon Laboratories:	
Scour Stop for Pigs-----	6097	contact lens wetting solution--	6101
Brown Pharmaceutical Co.:		Mother Nature Co.:	
Pabacaine -----	6085	bath minerals-----	6090
Brown, T. J., Co.:		Myrtle Chemical Co.:	
Femone tablets-----	6104	arthritis remedy-----	6081
Burroughs, S. A.:		Nairn, J. S.:	
unassembled color lamp units- <sup>1</sup>	6120	Cos-Mel Honey-----	6111
Burroughville Specialties. <i>See</i>		Nairne, Chester H., Co.:	
Burroughs, S. A.		Nutrin vitamin and mineral capsules -----	6092
Chem-Tek, Inc.:		Napier, D. A.:	
Femone tablets-----	6104	Napier's 14 & 10 Vitamins- Minerals tablets, Napier's Special Formula tablets, Napier's Inhalant & Rubbing Oil, and Napier's Family Salve <sup>1</sup> -----	6089
Cowley Pharmaceuticals, Inc.:		Natural Plating Corp. <i>See</i> Suk- acev, L. P.	
Beautycare capsules-----	6113	Nome Distributing Co. <i>See</i> Tos- tenrud, G. W.	
Dean Rubber Co.:		O'Conner Bros. Drug Co.:	
prophylactics -----	6105	Dex-A-Diet tablets-----	6108
Dean Rubber Mfg. Co.:		Parthenon Pharmaceuticals, Inc.:	
prophylactics -----	6105	Beautycare capsules-----	6113
deLendrecie, O. J., Co.:		Philadelphia Ampule Laborator- ies, Inc.:	
Swedish Masseur Contour Vi- brator -----	6118	Pabacaine -----	6085
du Pont de Nemours, E. I., & Co.:		Physicians Drug & Supply Co.:	
terephthalic acid (Dupont TPA) -----	6099	terpin hydrate-----	6100
Durr Products, Inc.:		Profile Slenderizing Salons:	
Li-Folic-B <sub>12</sub> -----	6103	Slenderoll device-----	6117
Eastco, Inc.:		RC Enterprises:	
Sulfodene Medication (veteri- nary) -----	6106	Allure (B-Former) cream and Fountain of Youth cream--	6094
Eastern Laboratories, Inc.:		Remington Research, Inc.:	
Entero-Sol Powder-----	6087	Swedish Masseur Contour Vibrator -----	6118
Elijah, Clinton:		Remington Sales:	
Electro-Galvanic Bracelets----	6119	Swedish Masseur Contour Vibrator -----	6118
F. H. J. Laboratories, Inc.:			
Obes-Ebb tablets and thyroid tablets -----	6102		
General Pharmacal Co., Inc.:			
Obes-Ebb tablets and thyroid tablets -----	6102		
Health Products, Inc.:			
Flex-O-Matic massage cushion--	6116		
Hope Co.:			
Hope's Worm-Rid-----	6086		
House of Nutritive Formulas:			
vitamin products-----	6095		

<sup>1</sup> (6089, 6120) Prosecution contested.

	N.J. No.		N.J. No.
Rollins, Ben C., Co.:		Vegetrates Co.:	
Entero-Sol Powder-----	6087	Vegetrates lecithin with vita-	
Schaffer Laboratories:		min D-----	6110
Phylorinol -----	6109	Vineland Poultry Laboratories:	
Slendora Salons, Inc.:		terephthalic acid-----	6098
Weight-away tablets-----	6107	Vitamin Center:	
Starlite Products:		vitamin capsules-----	6114
Allure (B-Former) cream and		Vitarene Co.:	
Fountain of Youth cream--	6094	Nutrin vitamin and mineral	
Storek Pharmaceuticals, Inc.:		capsules -----	6092
Li-Folic-B <sub>12</sub> -----	6103	Vydagen Products:	
Struhl, Morris, Inc.:		Vydagen laxative compound--	6091
Beautiaire massage pillow----	6115	Ward, Mrs. Mabel:	
Sukacev, L. P.:		Allure bust development	
Electro-Galvanic Bracelets----	6119	device -----	6082
Tops Products Co.:		Weight Away Sales Co.:	
Allure (B-Former) cream and		Weight-away tablets-----	6107
Fountain of Youth cream--	6094	Wolfgram, H. A.:	
Tostenrud, G. W.:		bath minerals-----	6090
Electro-Galvanic Bracelets----	6119	Woodard Laboratories:	
Tracy's Professional Service:		Tracy Body-Tone liniment---	6112
Tracy Body-Tone liniment----	6112		



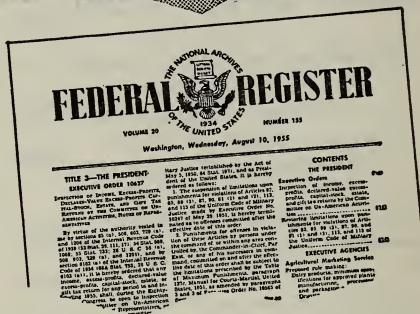
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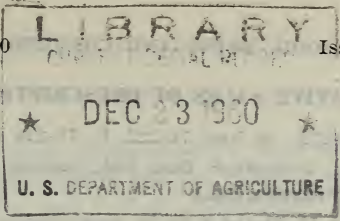


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732Nd



**U.S. Department of Health, Education, and Welfare**  
**FOOD AND DRUG ADMINISTRATION**

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**NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD,  
DRUG, AND COSMETIC ACT**

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

6121-6160

**DRUGS AND DEVICES**

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The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs which are required at time of interstate shipment to bear a label containing the statement "Caution: Federal law prohibits dispensing without prescription," and which were dispensed after such shipment without a prescription or by refilling a prescription without authorization. This dispensing was contrary to Section 503(b) (1) and thereby resulted in the dispensed drugs being misbranded while held for sale.

Published by direction of the Secretary of Health, Education, and Welfare.

**GEO. P. LARRICK, *Commissioner of Food and Drugs.***

**WASHINGTON, D.C., November 25, 1960.**

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## VIOLATIVE SALES OF PRESCRIPTION DRUGS

6121. (F.D.C. No. 44272. S. Nos. 71-222, P, 71-224 P, 71-226 P.)

INFORMATION FILED: 3-16-60, S. Dist. Ind., against Gladys Lee (an employee of a truck stop at Straughn, Ind.).

CHARGE: Between 8-13-59 and 8-20-59, *amphetamine sulfate tablets* were dispensed 3 times without a prescription.

PLEA: Guilty.

DISPOSITION: 6-7-60. 18 months imprisonment suspended, and probation for 1 year.

6122. (F.D.C. No. 44295. S. No. 56-239 P.)

INFORMATION FILED: 5-17-60, W. Dist. Mo., against Harold Etter, Roeland Park, Kans.

CHARGE: On 8-25-59, *amphetamine sulfate tablets* were dispensed twice at a truck stop in Jackson County, Mo., without a prescription.

PLEA: Guilty.

DISPOSITION: 6-3-60. Sentence of 18 months in jail, plus costs.

6123. (F.D.C. No. 42484. S. Nos. 84-006 P, 84-011/3 P, 84-015/6 P, 84-019/20 P, 96-721 P.)

INFORMATION FILED: 1-14-60, Dist. Wyo., against Theodore R. Finney, D.O., and his wife, Etta Lee Finney, Rock Springs, Wyo.

CHARGE: Between 9-17-59 and 12-18-59, *amphetamine sulfate tablets* were dispensed 6 times and *secobarbital sodium capsules* were dispensed 3 times without a prescription.

PLEA: Guilty by Theodore R. Finney to all counts of the information and by Etta Lee Finney to one count involving *amphetamine sulfate tablets*, and one count involving *secobarbital sodium capsules*.

DISPOSITION: 5-27-60. Theodore R. Finney—probation for 2 years. Etta Lee Finney—probation for 1 year.

6124. (F.D.C. No. 44284. S. Nos. 59-532/4 P.)

INFORMATION FILED: 3-27-60, E. Dist. N.C., against George Harris Eason, Wilmington, N.C.

CHARGE: Between 5-31-59 and 6-11-59, *amphetamine sulfate tablets* were dispensed 3 times without a prescription.

PLEA: Guilty.

DISPOSITION: 5-24-60. Defendant was fined \$250, given a sentence of 9 months in jail which was suspended, and placed on probation for 2 years.

6125. (F.D.C. No. 44282. S. Nos. 15-753 P, 71-205 P, 71-228 P, 71-240 P, 71-245 P.)

INFORMATION FILED: 3-4-60, S. Dist. Ind., against William Albert Bork, t/a Bork's Truck Stop, Muncie, Ind.

CHARGE: Between 8-27-59 and 10-29-59, *amphetamine sulfate tablets* were dispensed 5 times without a prescription.

PLEA: Guilty.

DISPOSITION: 5-10-60. Fine of \$500 on each of the 5 counts of the information, plus costs. Fines on counts 3, 4, and 5 of the information were suspended.



6126. (F.D.C. No. 43682. S. Nos. 1-201 P, 1-203 P, 1-247 P, 56-281 P, 56-283 P, 56-334 P.)

INFORMATION FILED: 11-10-59, against Kelley's Truck Stop (a partnership), Milner, Ga., Henry Johnson Kelley and Guy Franklin Kelley (partners).

CHARGE: Between 12-18-58 and 3-25-59, *amphetamine sulfate tablets* were dispensed 6 times (6 counts) without a prescription.

PLEA: Not guilty by the partnership to all counts; by Guy Franklin Kelley to 4 counts; and by Henry Johnson Kelley to 2 counts.

DISPOSITION: On 5-2-60, the case came on for trial before the court and the jury. On the same date, the jury returned a verdict of guilty. The partnership was fined \$1.00 and the individuals were each fined \$350 and placed on probation for 3 years.

6127. (F.D.C. No. 40606. S. Nos. 65-019 M, 16-213 P.)

INFORMATION FILED: 2-4-58 and 1-5-59, E. Dist. Ky., against George H. Wilhelmi, t/a Wilhelmi Pharmacy, Newport, Ky. The two informations were consolidated on 1-21-59.

CHARGE: Between 8-5-57 and 5-31-58, *amphetamine sulfate tablets* were dispensed once without authorization from a prescriber, and *Butazolidin tablets* were dispensed once upon request for a prescription refill without authorization from the prescriber.

PLEA: Guilty.

DISPOSITION: After the first case was filed, the defendant filed a motion for a bill of particulars to obtain from the Government the following information:

- (1) the identity and address of the Government informer;
- (2) the quantity of tablets and capsules involved in each act of dispensing;
- (3) the place of origin from whence the tablets and capsules were shipped in interstate commerce; and
- (4) the occupation of the Government informer;

On 3-10-58, the court granted requests 1, 2, and 4, and dismissed request 3. Thereafter, the second information was filed, and after the informations were consolidated the defendant pled guilty. On 10-1-59, the defendant was fined \$300, plus costs.

6128. (F.D.C. No. 43681. S. Nos. 1-202 P, 1-208 P, 1-236 P, 2-159 P, 56-282 P, 56-296 P.)

INDICTMENT RETURNED: 11-3-59, N. Dist. Ga., against Preston C. Williams, t/a Dixie 66 Truck Stop, Orchard Hill, Ga., Louise Cook Worsham and Mrs. Douglas (Frankie) Stewart (employees).

CHARGE: Between 11-19-58 and 1-12-59, *amphetamine sulfate tablets* were dispensed 6 times (6 counts) without a prescription.

PLEA: Nolo contendere by Williams to all counts and by Worsham and Stewart to 2 counts each.

DISPOSITION: 5-3-60. Williams—\$300 fine and probation for 3 years; Worsham and Stewart were each placed on probation for 2 years.

6129. (F.D.C. No. 44286. S. No. 18-548 P.)

INFORMATION FILED: 3-8-60, Dist. N. Mex., against Buster Lackey (an employee of a truck stop at Las Cruces, N. Mex.).

CHARGE: On 11-7-58, *amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 4-8-60. \$150 fine, 1 year jail sentence suspended, and probation for 1 year.

6130. (F.D.C. No. 43716. S. No. 54-483 P.)

INFORMATION FILED: 2-9-60, E. Dist. Mo., against Thomas Pate, Hayti, Mo.

CHARGE: On 1-13-59, *amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 4-25-60. \$1,000 fine, plus costs.

6131. (F.D.C. No. 43261. S. Nos. 1-205 P, 2-124 P, 56-284/5 P.)

INDICTMENT RETURNED: 11-2-59, N. Dist. Ga., against John Lee Wells (an employee of a truck stop in Clayton County, Mountain View, Ga.).

CHARGE: Between 11-2-58 and 1-7-59, *amphetamine sulfate tablets* were dispensed 4 times without a prescription.

PLEA: Guilty.

DISPOSITION: 1-13-60. Probation for 2 years.

6132. (F.D.C. No. 44271. S. Nos. 45-671/2 P.)

INFORMATION FILED: 2-25-60, Dist. N. Mex., against Lou "Chief" Padgett (an employee of a truck stop at Las Cruces, N. Mex.).

CHARGE: Between 11-16-58 and 11-18-58, *amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 3-11-60. \$50 fine and probation for 1 year.

6133. (F.D.C. No. 44269. S. Nos. 45-662/3 P.)

INFORMATION FILED: 2-25-60, Dist. N. Mex., against Joe Rodgers (an employee of a truck stop at Las Cruces, N. Mex.).

CHARGE: On 11-14-58, *amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 3-11-60. \$250 fine, 1 years imprisonment suspended, and probation for 1 year.

6134. (F.D.C. No. 43714. S. No. 54-497 P.)

INFORMATION FILED: 2-9-60, E. Dist. Mo., against Gerald S. Kellett, t/a Kellett Bros. Service Station, Sikeston, Mo.

CHARGE: On 2-4-59, *amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 3-19-60. \$500 fine, plus costs.

6135. (F.D.C. No. 43713. S. No. 75-768 P.)

INFORMATION FILED: 2-9-60, E. Dist. Mo., against John W. Cross, t/a Cross Oil Co., Wyatt, Mo.

CHARGE: On 8-13-59, *amphetamine sulfate tablets*, which had been fabricated in the State of Missouri from an unknown quantity of amphetamine that had been shipped in interstate commerce, were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 3-19-60. \$500 fine, plus costs.

6136. (F.D.C. No. 43262. S. Nos. 1-536 P, 1-538 P, 1-543 P.)

INDICTMENT RETURNED: 11-3-59, N. Dist. Ga., against Edward C. Shumate, College Park, Ga.

CHARGE: Between 10-2-58 and 10-23-58, *amphetamine sulfate tablets* were dispensed 3 times without a prescription.

PLEA: Guilty.

DISPOSITION: 11-17-59. Probation for 2 years.

6137. (F.D.C. No. 43225. S. Nos. 2-966/9 P, 44-103/4 P.)

INFORMATION FILED: 8-14-59, S. Dist. Fla., against Frederick J. Auwers, M.D., Jacksonville, Fla.

CHARGE: Between 8-20-58 and 10-1-58, *dextro-amphetamine sulfate tablets* and *pentobarbital sodium tablets* were each dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 6-3-60. \$500 fine and probation for 3 years.

6138. (F.D.C. No. 43705. S. Nos. 36-317/9 P, 75-761/2 P.)

INFORMATION FILED: 2-3-60, E. Dist. Ill., against Glen Jones, t/a Glen Jones Truck Stop, Future City, Ill.

CHARGE: Between 3-2-59 and 7-25-59, *dextro-amphetamine sulfate tablets* were dispensed 3 times and *amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 3-15-60. \$500 fine and 2 years probation.

6139. (F.D.C. No. 41754. S. Nos. 81-896 M, 81-899/900 M, 82-523/4 M, 82-526 M.)

INDICTMENT RETURNED: 1-7-59, N. Dist. Tex., against First Street Drug Store, Inc., Irving, Tex., and Fred E. Simmons (president).

CHARGE: Between 9-30-57 and 11-20-57, *dextro-amphetamine sulfate tablets* were dispensed 5 times and *cortisone acetate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 10-14-59. Corporation and individual—\$250 fine each.

6140. (F.D.C. No. 43666. S. Nos. 2-651/4 P.)

INFORMATION FILED: 10-15-59, M. Dist. N.C., against Bill's Truck Stop (a partnership), Linwood, N.C., Billy F. Walser (partner), and Earl Nelson Chunn (employee).

CHARGE: Between 5-24-58 and 5-26-58, *methamphetamine hydrochloride tablets* were dispensed 4 times without a prescription.

PLEA: Guilty.



DISPOSITION: 4-19-60. Partnership—\$1,000 fine; Walser—\$1,000 fine and probation for 5 years; Chunn—\$200 fine and probation for 2 years.

6141. (F.D.C. No. 42490. S. No. 46-621/8 P.)

INFORMATION FILED: 5-24-60, W. Dist. La., against **James W. Flynn, t/a Bastrop Drug Co., and George H. Jarrell (pharmacist), Bastrop, La.**

CHARGE: Between 5-12-59 and 5-27-59, *tablets containing a mixture of amobarbital and amphetamine sulfate* and *tablets containing reserpine* were each dispensed 3 times upon requests for prescription refills without obtaining authorization from the prescriber, and *Equanil tablets and tablets containing a mixture of amobarbital and amphetamine sulfate* were each dispensed once without a prescription.

PLEA: Guilty by Flynn to all counts and by Jarrell to two counts involving the *tablets containing reserpine*.

DISPOSITION: 6-1-60. Flynn—\$800 fine; Jarrell—\$200 fine. The fines were suspended and each defendant was placed on probation for 5 years.

6142. (F.D.C. No. 38155. S. Nos. 4-334 M, 4-358/9 M, 4-426/7 M.)

INFORMATION FILED: 12-11-57, W. Dist., N.Y., against *Saratoga Pharmacy (a partnership), Rochester, N.Y., and Patrick DeCillis (pharmacist)*.

CHARGE: Between 1-31-55 and 4-4-55, *pentobarbital sodium capsules* were dispensed once and *Metadren Linguets* and *Dexedrine Sulfate tablets* were each dispensed twice upon requests for prescription refills without authorization by the prescriber.

PLEA: Nolo contendere.

DISPOSITION: 5-2-60. Partnership—\$400 fine; DeCillis—\$100 fine.

6143. (F.D.C. No. 43679. S. Nos. 45-190/3 P, 45-197/8 P, 45-445 P, 45-447 P.)

INFORMATION FILED: 11-10-59, Dist. Idaho, against **Nixon Drug Store (a partnership), Blackfoot, Idaho, Charles S. Nixon (partner), and Cecil Pendlebury (partner)**.

CHARGE: Between 10-18-58 and 12-16-58, *Dexedrine Spansule capsules* were dispensed 3 times and *thyroid tablets* were dispensed 5 times without a prescription.

PLEA: Guilty—by the partnership to all counts; by Pendlebury to 2 counts involving *Dexedrine Spansule capsules* and *thyroid tablets*; by Nixon to 2 counts involving *Dexedrine Spansule capsules* and 4 counts involving *thyroid tablets*.

DISPOSITION: 2-24-60. Partnership—\$400 fine; Nixon—\$400 fine; Pendlebury—\$200 fine.

6144. (F.D.C. No. 43704. S. Nos. 42-743 P, 42-745/7 P, 42-752 P.)

INFORMATION FILED: 1-14-60, E. Dist. Wash., against **Virgil Elliott, Asa Benton McDaniel, and Francis W. Delaney (pharmacists), Spokane, Wash.**

CHARGE: Between 1-30-59 and 2-4-59, *tablets containing Allylisobutylbarbituric acid*, were dispensed 4 times, and *Seconal Sodium capsules* were dispensed once upon requests for prescription refills without authorization by a prescriber.

PLEA: Guilty by Elliott to 2 counts and by Delaney and McDaniel to 1 count each involving *tablets containing Allylisobutylbarbituric acid*, and by McDaniel to the count involving *Seconal Sodium capsules*.

DISPOSITION: 2-17-60. Elliott—\$600 fine and probation for 1 year; McDaniel—\$600 fine, of which \$300 was suspended; Delaney—\$300 fine.

6145. (F.D.C. No. 42407. S. Nos. 30-016 P, 30-018 P, 30-938 P, 31-143 P.)

INFORMATION FILED: 11-18-59, S. Dist. N.Y., against Louis Malkin, t/a Charles Pharmacy, Bronx, N.Y., and Louis A. Iorio (pharmacist).

CHARGE: Between 3-13-58 and 5-15-58, *Metandren Linguets* were dispensed twice upon requests for prescription refills without authorization by the prescriber, and *Thorazine tablets* and *Dexedrine Sulfate tablets* were each dispensed once without a prescription.

PLEA: Guilty by Malkin to all counts and by Iorio to the counts involving the *Metandren Linguets*.

DISPOSITION: 4-7-60. Malkin—\$1,500 fine, 1 years imprisonment suspended, and probation for 2 years; Iorio—1 years imprisonment suspended, and probation for 1 year.

6146. (F.D.C. No. 42401. S. Nos. 29-832 P, 30-947/8 P, 30-957/8 P.)

INFORMATION FILED: 2-24-60, S. Dist. N.Y., against B.M.T. Pharmacy, Inc., New York, N.Y., Sydney Nestle (president of the corporation), and Chris Melendez (clerk).

CHARGE: Between 2-7-58 and 2-25-58, *methyltestosterone tablets* (count 1) were dispensed once, and *Metandren Linguets* (counts 2 and 3) and *amphetamine sulfate tablets* (counts 4 and 5) were each dispensed twice without a prescription.

PLEA: Guilty by Melendez to counts 1 and 2; not guilty by the corporation to all counts; and by Nestle to counts 1, 3, 4, and 5.

DISPOSITION: On 3-8-60, Melendez was given a sentence of 5 months in jail which was suspended and was placed on probation for 3 years.

On 2-25-60, the case against the corporation and Nestle came on for trial before the court and a jury. On 3-2-60, the jury returned a verdict of guilty. Thereafter, on 3-8-60, the corporation was fined \$600; and Nestle was fined \$600, given a 6 months jail sentence which was suspended, and placed on probation for 3 years.

6147. (F.D.C. No. 43239. S. Nos. 33-663 P, 33-672 P, 33-674 P, 33-682 P, 33-687 P, 33-692 P, 33-694 P.)

INFORMATION FILED: 1-7-60, S. Dist. N.Y., against Howard K. Ganbarg (partner in the Leo Ganbarg Pharmacy), New York, N.Y.

CHARGE: Between 12-9-58 and 1-14-59, *chloramphenicol capsules*, *Doriden tablets* and *dextro-amphetamine sulfate tablets* were each dispensed 1 time upon requests for prescription refills without authorization from a prescriber, and *Gantrisin tablets*, *Metandren tablets*, *Cyclogesterin tablets* and *Abvocilin* were each dispensed 1 time without a prescription.

PLEA: Guilty.

DISPOSITION: 3-29-60. \$1,000 fine.

6148. (F.D.C. No. 43728. S. Nos. 5-881/4 P, 5-886/8 P.)

INFORMATION FILED: 3-15-60, E. Dist. N.C., against Brodie D. Arnold, t/a Arnold Rexall Drugs, Raleigh, N.C., Eugene M. Ussery (pharmacist), and Ruben Emory (employee).

CHARGE: Between 3-7-59 and 5-5-59, *hexobarbital tablets* were dispensed 6 times (counts 1 through 5 and count 7) and *Dartal tablets* (count 6) were dispensed once without a prescription.

PLEA: Guilty by Ussery to counts 5 and 6; by Emory to counts 1 through 4; and by Arnold to count 7.

DISPOSITION: 4-25-60. Arnold was fined \$200; Ussery was fined \$200; and Emory was fined \$100. Each defendant also was placed on probation for 2 years.

6149. (F.D.C. No. 43690. S. Nos. 59-471/5 P.)

INFORMATION FILED: 12-7-59, E. Dist. N.C., against Frank W. Heslep, Beaufort, N.C.

CHARGE: Between 4-17-59 and 5-27-59, *Equanil tablets* were dispensed 4 times and *Meticorten tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 4-19-60. \$200 fine and 2 years probation.

6150. (F.D.C. No. 43724. S. Nos. 5-841/6 P.)

INFORMATION FILED: 2-24-60, E. Dist. N.C., against Bob Clark Pharmacy, Inc., Havelock, N.C., and Robert L. Clark (president).

CHARGE: Between 3-24-59 and 5-27-59, *Equanil tablets* were dispensed 5 times and *Meticorten tablets* were dispensed once without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 4-18-60. After the pleas were entered, a motion for acquittal of the corporation was granted. The individual was fined \$200 and placed on probation for 2 years.

6151. (F.D.C. No. 43706. S. Nos. 5-822/5 P.)

INFORMATION FILED: 3-2-60, E. Dist. N.C., against Thomas H. Suddreth (manager of the Standard Drug Co., Store No. 2), Kinston, N.C.

CHARGE: Between 3-24-59 and 5-27-59, *Equanil tablets* and *tablets containing phenobarbital* were each dispensed twice without prescription.

PLEA: Not guilty.

DISPOSITION: On 4-18-60, the case came on for trial before the court without a jury. The defendant was found guilty, fined \$300, and placed on probation for 2 years.

6152. (F.D.C. No. 43703. S. Nos. 59-501/5 P.)

INFORMATION FILED: 1-8-60, E. Dist. N.C., against Daniel S. Pigott (partner in the partnership of Carteret Drug Store), Morehead City, N.C.

CHARGE: Between 4-17-59 and 5-27-59, *Equanil tablets* were dispensed 4 times and *Meticorten tablets* were dispensed once without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 4-19-60. \$200 fine and 2 years probation.

6153. (F.D.C. No. 43233. S. Nos. 1-913/4 P, 1-918/9 P, 1-926 P, 1-933/4 P, 1-947 P.)

INFORMATION FILED: 10-15-59, W. Dist. N.C., against Clarence Little Rhyne, t/a Rhyne Drug Store, Charlotte, N.C., and Arlie Gene Maddox (employee).



CHARGE: Between 7-16-58 and 9-6-58, *pentobarbital sodium capsules* (counts 1, 3, and 6) and *Dewedrine Sulfate tablets* (counts 2, 4, and 7) were each dispensed 3 times upon request for prescription refills without authorization from the prescriber, and *Premarin tablets* were dispensed twice without a prescription.

PLEA: Guilty by Rhyne on counts 1, 2, 3, 4, 5, and 8 and by Maddox on counts 6 and 7.

DISPOSITION: 5-16-60. Rhyne—\$600 fine; Maddox—\$200 fine.

6154. (F.D.C. No. 42489. S. Nos. 46-631/3 P, 46-635/6 P, 46-638/9 P.)

INFORMATION FILED: 5-24-60, W. Dist. La., against Maurice Hugo Spier (partner in Spier Drug Co.), and Richard J. Webb (employee), Bastrop, La.

CHARGE: Between 5-13-59 and 5-27-59, *Nembutal Sodium capsules* were dispensed 4 times upon request for a prescription refill (counts 1, 2, 5, and 7) without obtaining authorization from the prescriber, and *Miltown tablets* (counts 3 and 4) were dispensed twice and *Dewedrine Sulfate tablets* (count 6) were dispensed once without a prescription.

PLEA: Guilty by Spier to counts 5 and 6 and by Webb to the remaining counts.

DISPOSITION: 6-1-60. Spier—\$200 fine; Webb—\$500 fine. The fines were suspended and each defendant was placed on probation for 5 years.

6155. (F.D.C. No. 43727. S. Nos. 59-671 P, 59-675 P, 59-677 P, 59-679 P.)

INFORMATION FILED: 3-15-60, E. Dist. N.C., against James M. Hall, Jr., t/a Hall's Drug Store, Wilmington, N.C., and Julius F. Howard (pharmacist).

CHARGE: Between 5-14-59 and 6-12-59, *penicillin G potassium tablets* were dispensed 3 times and *tablets containing phenobarbital* were dispensed once without a prescription.

PLEA: Not guilty by Hall to all counts of the information and by Howard to 1 count involving *penicillin G potassium tablets* and to the count involving *tablets containing phenobarbital*.

DISPOSITION: On 6-6-60, the case came on for trial before the court without a jury. On 6-7-60, the court found the defendants guilty. Hall was fined \$300 and Howard was fined \$100 and both defendants were placed on probation for 2 years.

6156. (F.D.C. No. 44288. S. Nos. 50-042 P, 71-236/7 P.)

INFORMATION FILED: 3-4-60, S. Dist. Ind., against Dwight Barker (an employee of a truck stop at Indianapolis, Ind.).

CHARGE: Between 9-16-59 and 9-21-59, *desoxyephedrine hydrochloride tablets* were dispensed 3 times without a prescription.

PLEA: Guilty.

DISPOSITION: 5-10-60. Fine of \$500 on each of the 3 counts of the information, plus costs. Fines on counts 2 and 3 of the information were suspended.

6157. (F.D.C. No. 44283. S. Nos. 71-225 P, 71-231 P.)

INFORMATION FILED: 3-4-60, S. Dist. Ind., against Bertha E. Dollahan, t/a Twilite Inn, Shelburn, Ind.

CHARGE: Between 8-26-59 and 9-3-59, *desoxyephedrine hydrochloride tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION : 5-10-60. Fine of \$500 on each of the 2 counts of the information, plus costs. Fine on count 2 was suspended.

6158. (F.D.C. No. 44280. S. Nos. 5-831/2 P, 5-834/7 P.)

INFORMATION FILED : 3-21-60, E. Dist. N.C., against Alexander L. Hogan, t/a **Hogan's Pharmacy, Kinston, N.C.**

CHARGE : Between 3-17-59 and 6-9-59, *Pro-Banthine tablets* were dispensed 4 times and *Dartal tablets* and *Equanil tablets* were each dispensed once without a prescription.

PLEA : Not guilty.

DISPOSITION : On 4-18-60, the case came on for trial before the court without a jury. The defendant was found guilty, fined \$500, and placed on probation for 2 years.

6159. (F.D.C. No. 43700. S. Nos. 59-661/7 P.)

INFORMATION FILED : 12-31-59, E. Dist. N.C., against Arthur D. Wall, t/a **Grifton Pharmacy, Grifton, N.C.**

CHARGE : Between 4-30-59 and 6-8-59, *Ergoapiol with savin capsules*, *Aphrodex capsules*, *Testacoids tablets*, and *capsules containing amytal* were each dispensed once, and *Meticorten tablets* were dispensed 3 times without a prescription.

PLEA : Nolo contendere.

DISPOSITION : 5-9-60. \$300 fine and probation for 2 years.

6160. (F.D.C. No. 43726. S. Nos. 5-901/7 P.)

INFORMATION FILED : 2-16-60, E. Dist. N.C., against George David Grimes, t/a **David Grimes Drug Store, Robersonville, N.C.**

CHARGE : Between 3-11-59 and 5-13-59, *Benzedrine Sulfate tablets*, *Equanil tablets*, and *pentobarbital sodium capsules* were each dispensed twice, and *Pen-Tabs* (penicillin G potassium tablets) were dispensed once without a prescription.

PLEA : Guilty.

DISPOSITION : 4-26-60. \$200 fine and probation for 2 years.

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<sup>1</sup> (6126, 6151, 6158) Prosecution contested.

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<sup>1</sup> (6126, 6151, 6158) Prosecution contested.



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<sup>1</sup> (6126, 6151, 6158) Prosecution contested.

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<sup>1</sup> (6126, 6151, 6158) Prosecution contested.

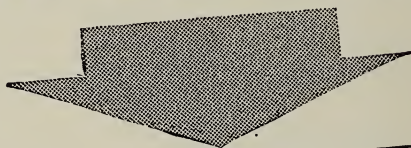




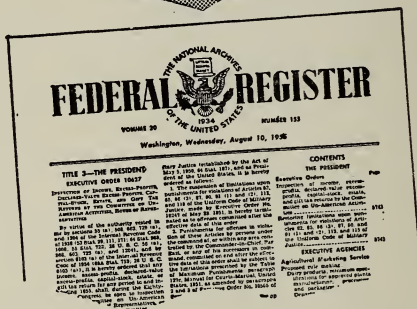


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## U.S. Department of Health, Education, and Welfare

## FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD,  
DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

6161-6200

## DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were adulterated or misbranded within the meaning of the Act when introduced into and while in interstate commerce or while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings in which decrees of condemnation were entered after default or consent; (2) a criminal proceeding terminated upon a plea of guilty; and (3) an injunction proceeding terminated upon the entry of a consent decree of temporary injunction. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation, and the criminal and injunction proceedings are against the *firms* or *individuals* charged to be responsible for violations.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D.C., December 13, 1960.

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\*For drugs in violation of prescription labeling requirements, see No. 6163; omission of, or unsatisfactory, ingredient statements, Nos. 6172, 6175; failure to comply with the packaging requirements of an official compendium, No. 6175; failure to bear a label containing an accurate statement of the quantity of the contents, No. 6172; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, No. 6172; cosmetic, actionable under the drug provisions of the Act, No. 6165.



SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS  
REPORTED IN D.D.N.J. NOS. 6161-6200

*Adulteration*, Section 501(b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia), and its strength differed from, and its quality fell below, the standard set forth in such compendium; and Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength differed from, or its purity or quality fell below, that which it purported or was represented to possess.

*Misbranding*, Section 502(a), the labeling of the article was false and misleading; Section 502(b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; Section 502(e) (2), the article was a drug not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient; Section 502(f), the labeling of the article failed to bear (1) adequate directions for use; and (2) adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form as are necessary for the protection of users; Section 502(g), the article purported to be a drug, the name of which is recognized in an official compendium (United States Pharmacopeia), and it was not labeled as prescribed therein; Section 502(j), the article was dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof; and Section 503(b) (4), the article was a drug subject to 503(b) (1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

*New-drug violation*, Section 505(a), the article was a new drug within the meaning of Section 201(p), which was introduced into interstate commerce, and an application filed pursuant to Section 505(b) was not effective with respect to such drug.

DEVICES ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN  
USED ACCORDING TO DIRECTIONS

**6161. Allure bust development device.** (F.D.C. No. 44114. S. No. 26-112 R.)  
QUANTITY: 1 device at Lompoc, Calif.

SHIPPED: 1-17-60, from Alamogordo, N. Mex., by Mrs. Patra Roland.

LABEL IN PART: (Metal plate on device) "Allure Mfd. by Allure Incorporated, Hollywood, Calif., Model 31358, Serial No. 1032."

RESULTS OF INVESTIGATION: The article consisted of rubber-ringed plastic cups of various sizes which had small openings for connection to rubber hoses attached to an air compressor or pump operated by an electric motor. Attached to the compressor was a pressure regulator, a vacuum gauge, and a valve to regulate the amount of vacuum produced in each of the two breast cups.

While in use, the plastic cups were pressed over the breasts against the chest and the rubber-ringed edge formed an airtight seal. The air compressor was then operated to form a vacuum inside the cups to exercise the breasts by contraction and relaxation.

The air compressor and accessory equipment were contained in a metal cabinet 36" x 22" x 18".

**LIBELED:** 4-5-60, S. Dist. Calif.

**CHARGE:** 502(f) (1)—when shipped, the labeling of the article failed to bear adequate directions for use for the purposes for which it was intended, namely, for developing the human breast; and 502(j)—the labeling of the article was dangerous to health when used in the dosage, or with the frequency or duration, prescribed, recommended, or suggested in the labeling thereof.

**DISPOSITION:** 5-10-60. Default—destruction.

**6162. Ray of Life device.** (F.D.C. No. 44011. S. No. 51-138 P.)

**QUANTITY:** 11 devices at St. Paul, Minn., and 2 devices at Stillwater, Minn., in possession of Henry Amundson.

**SHIPPED:** 5-20-58, from Racine, Wis.

**LABEL IN PART:** "Electronic High Frequency Generator \* \* \* The Ray of Life."

**RESULTS OF INVESTIGATION:** The device was a type of electronic high-frequency generator which produced a glow discharge in a variety of gas-filled glass applicators.

**LIBELED:** 12-29-59, Dist. Minn.

**CHARGE:** 502(f) (1)—while held for sale, the labeling of the article failed to bear adequate directions for use; and 502(j)—the article was dangerous to health when used as directed.

**DISPOSITION:** 3-23-60. Consent—claimed by Henry Amundson, Stillwater, Minn., and dismantled.

## NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

### DRUG FOR HUMAN USE

**6163. Les-Wate capsules.** (F.D.C. No. 44370. S. No. 85-084 P.)

**QUANTITY:** 5 cans, 5,000 capsules each, and 8 display cartons, each containing 4 30-capsule btl., at Baltimore, Md., in possession of Reyman Drug Co., Inc.

**SHIPPED:** 1-29-60, from Philadelphia, Pa., by Richlyn Laboratories.

**LABEL IN PART:** (Can) "Phenylpropanolamine HCl Prolongsul. Each Prolongsul contains: Phenylpropanolamine HCl 75 mg. \* \* \* Caution: Federal law prohibits dispensing without prescription. Lot No. 9919 Richlyn Laboratories, Philadelphia, Pa., (btl.) "Les-Wate Capsule-A-Day to Melt Fat away Les-Wate Laboratories, Baltimore, Md. Distributor \* \* \* Each capsule contains: Phenylpropanolamine HCl. 75 mg. released gradually and equivalent to 3 doses over a period of approximately 8 hours."

**RESULTS OF INVESTIGATION:** The article in the bottles was repacked and relabeled by the dealer from bulk stock shipped as described above.

**LIBELED:** 3-9-60, Dist. Md.

**CHARGE:** 502(a)—while held for sale, the name "Les-Wate" and other statements on the label of the article contained false and misleading representations that the article was effective for weight reduction; 503(b) (4)—when shipped, the label bore the statement "Caution: Federal law prohibits dispensing without a prescription" and the article was a drug not subject to section 503(b) (1); and 505(a)—the article was a new drug and an application filed pursuant to 505(b) was not effective with respect to such drug.

**DISPOSITION:** 4-1-60. Default—destruction.

## DRUGS FOR VETERINARY USE

**6164. Cardiobee 15 injection and Cardiobee 15 solution.** (F.D.C. No. 44256 S. Nos. 72-340/2 P.)

QUANTITY: 163 10-cc. vials and 71 30-cc. vials of *Cardiobee 15 injection* and 11 1-pt. btl. of *Cardiobee 15 solution* at Hialeah, Fla.

SHIPPED: 3-10-59 and 8-7-59, from San Francisco, Calif., by John Beard Memorial Foundation.

LABEL IN PART: (Vial) "Multiple Dose Sterile Vial Cardiobee 15 Injection Each 10 cc. contains 100 mg. of Na-Glucono-di (N-Diisopropylamino) Acetate Benzyl Alcohol .2% Physiological Saline Solution q.s. For Veterinary Use Only Dist. by—Zirin Enterprises, Hialeah, Florida" and "Cardiobee 15 Solution \* \* \* For Oral Use Each ounce contains 50 mg. of Na-Glucono-Di (N-Diisopropylamino) Acetate Water q.s. For Veterinary Use Only \* \* \* Distributed by Zirin Enterprises—Hialeah, Florida."

LIBELED: About 3-17-60, S. Dist. Fla.

CHARGE: 505(a)—the articles, when shipped, were new drugs which may not be introduced into interstate commerce since applications filed pursuant to law were not effective with respect to such drugs.

DISPOSITION: 6-17-60. Default—destruction.

**DRUGS AND DEVICE ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS\***

**6165. Natural Formula 52 Sulphur Cream Lotion, Natural Formula 51 Sulphur Bath Concentrate, and Instant Sulphur Bath Concentrate.** (F.D.C. No. 43942. S. Nos. 83-501/3 P.)

QUANTITY: 766 2-oz. btl. of Formula 52; 5 cases, 24 8-oz. btl. each, of Formula 51; and 10 cases, 24 8-oz. btl. each, of *Instant Sulphur Bath Concentrate*, at Oklahoma City, Okla.

SHIPPED: Between 1-19-59 and 2-9-59, and other unknown dates during 1958 and 1959, from Park Ridge, Ill., by Trenkmann Laboratories.

LABEL IN PART: (Btl.) "Natural Formula 52 Sulphur Cream Lotion Skin Supplement \* \* \* Distributed by: K. V. Products Company \* \* \* Oklahoma City 18, Oklahoma," "Natural Formula 51 Sulphur Bath Concentrate \* \* \* Distributed by K. V. Products Company \* \* \* Oklahoma City 18, Okla.," and "Instant Sulphur Bath Concentrate \* \* \* Trenkmann Laboratories, Park Ridge, Illinois."

ACCOMPANYING LABELING: Leaflets entitled "At Last Science Discovers How To Put Natural Sulphur Into Perfect Solution!"

LIBELED: 12-30-59, W. Dist. Okla.

CHARGE: 502(a)—when shipped, the labeling of the articles contained false and misleading representations that the *Natural Formula 52 Sulphur Cream Lotion* contained sulfur which would completely penetrate and absorb into the skin; would keep the skin youthful; that it was hypo-allergenic; and that it replenished sulfur-hungry tissues and helped restore the sulfur balance of the skin; and that the *Natural Formula 51 Sulphur Bath Concentrate* and *Instant Sulphur Bath Concentrate* were an adequate and effective treatment for arthritis; rheumatism; lumbago; nervous fatigue; sore muscles; aching

\*See also Nos. 6161, 6162.



joints; bursitis; acne; eczema; dermatitis; psoriasis; allergies; and that it would relieve itching and burning irritations on hands, arms, and body; and would maintain a youthful skin and keep one free of pain, healthy, and young; and 502(f) (2)—the labeling of the *Natural Formula 52 Sulphur Cream Lotion* failed to bear such adequate warnings against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users since the article contained sulfur and its labeling failed to warn that if undue skin irritation developed or increased, the use of the article should be discontinued and a physician consulted.

DISPOSITION: 2-10-60. Default—destruction.

**6166. Mills Aloin, Cascara and Phenolphthalein Compound tablets.** (F.D.C. No. 44402. S. No. 25-404 R.)

QUANTITY: 1 drum of 72,096 tablets at Reseda, Calif., in possession of Mills Pharmaceutical Co.

SHIPPED: 12-4-59, from Portland, Oreg., by Don Hall Laboratories.

LABEL IN PART: (Drum) "Tablets Mills Aloin, Cascara & Phenolphthalein Compound."

RESULTS OF INVESTIGATION: The tablets, after their receipt at Reseda, Calif., were to be repacked, in the normal course of the dealer's business operations, into bottles labeled in part "28 Tablets 11901 Control No. Mills Aloin, Cascara & Phenolphthalein Compound D-4 \* \* \* Formula: Phenolphthalein 1 gr. Ext. Cascara  $\frac{1}{2}$  gr. Pepsin 1-3000  $\frac{1}{2}$  gr. Aloin  $\frac{1}{4}$  gr. Podophyllin  $\frac{1}{6}$  gr. Diastase of Malt  $\frac{1}{8}$  gr. Oleo Resin Ginger 1/100 gr. Directions: Adults \* \* \* Children \* \* \* Manufactured for Mills Pharmaceutical Co. Encino, California."

Examination showed that the article contained 1 grain of phenolphthalein, pepsin, aloin, and probably other plant extractive material.

LIBELED: 3-29-60, S. Dist. Calif.

CHARGE: 502(f)—the labeling of the article, when shipped and while held for sale, failed to bear (1) adequate directions for use and (2) a warning statement that use of the article should be discontinued when abdominal pain, nausea, vomiting, or other symptoms of appendicitis were present, that frequent or prolonged use of the article may result in dependence on laxatives, and that preparations containing phenolphthalein should not be used if a skin rash appeared.

DISPOSITION: 5-24-60. Consent—claimed by Mills Pharmaceutical Co. and relabeled.

**6167. Hunt's 3-Minute Balm.** (F.D.C. No. 44364. S. No. 88-146 P.)

QUANTITY: 504 2-oz. btl. at Morehead, Ky.

SHIPPED: On various dates between July 1959, and the week of 1-14-60, from Detroit, Mich., by Hunt Bros. Product Co.

LABEL IN PART: (Btl.) "Hunt Bros. Product Company 3-minute Balm \* \* \* Active Ingredients: Menthol, Methyl Salicylate \* \* \* Manufactured by Hunt Bros. Directions: Rub on affected parts."

ACCOMPANYING LABELING: Blue and yellow leaflets entitled "Hunt's 3-Minute Balm."

LIBELED: 3-8-60, E. Dist. Ky.

**CHARGE:** 502(a)—when shipped, the labeling accompanying the article contained false and misleading representations that the article was an adequate and effective treatment for arthritis, rheumatism, headache, sinusitis, toothache, sore throat, all muscular aches, soreness, lameness, and stiffness; and 502(f) (1)—the labeling of the article failed to bear a warning that the article should be kept out of the reach of children to avoid accidental poisoning, that its use should be discontinued if excessive irritation of the skin developed, and that users should avoid getting the articles into the eyes or on mucous membranes.

**DISPOSITION:** 4-19-60. Default—destruction.

**6168. Amphetamine tablets and barbiturate capsules.** (F.D.C. No. 44027. S. Nos. 65-377/8 P.)

**QUANTITY:** About 100,000 amphetamine tablets and 10,000 barbiturate capsules at Rock Springs, Wyo., in possession of T. R. Finney, D.O.

**SHIPPED:** Prior to 1-14-60, from outside the State of Wyoming.

**LIBELED:** 1-15-60, Dist. Wyo.

**CHARGE:** 502(f) (1)—while held for sale, the labels of the articles failed to bear adequate directions for use and the articles were not exempt from that requirement by regulations since they were prescription drugs which, although in the possession of a licensed practitioner, were not to be dispensed by such practitioner in the course of his professional practice as required by 503(b).

**DISPOSITION:** 4-19-60. Consent—claimed by Theodore R. Finney, D.O., Rock Springs, Wyo., and delivered to the Food and Drug Administration.

**6169. Vitamin C (ascorbic acid) tablets.** (F.D.C. No. 44156. S. Nos. 76-891 P, 76-893 P.)

**QUANTITY:** 1,488 cases, each containing 12 sets of 2 100-tablet btl. of vitamin C (100 mgms.), 735 cases, each containing 12 sets of 2 100-tablet btl. of vitamin C (250 mgms.), at Seattle, Wash., in possession of McKesson & Robbins, Inc.

**SHIPPED:** Between 8-18-59 and 11-12-59, from Bridgeport, Conn., by McKesson & Robbins, Inc.

**LABEL IN PART:** (Btl.) "McKesson's Ascorbic Acid Vitamin C U.S.P. \* \* \* Each tablet contains 100 [or "250"] milligrams of Ascorbic Acid \* \* \* McKesson & Robbins, Incorporated, New York, N.Y.—Bridgeport, Conn."

**ACCOMPANYING LABELING:** Leaflets entitled "History and Uses of Vitamin C."

**LIBELED:** 1-4-60, W. Dist. Wash.

**CHARGE:** 502(a)—when shipped and while held for sale, the labeling of the article contained false and misleading representations that the article was capable of neutralizing toxins (poisons); that it would act as a chemotherapeutic agent in infectious diseases; that it was effective to aid in relief of symptoms of colds, "flu," fever, sinus, and colds; to relieve muscular aches and pains; to treat and prevent bleeding gums, "pink toothbrush," sore gums, spongy gums, and loosening of the teeth; to regulate cholesterol content of the body; to treat and prevent heart disease; to treat acute alcoholism; to control and treat allergies, hay fever, etc.; to prevent the convulsive states of whooping cough and to reduce the duration, and to eliminate all complications of the disease; and to treat circulatory disorders, arteriosclerosis, and anemia; and that practically all adults and children are deficient in vitamin C; and 502

(f) (1)—the labeling of the article failed to bear adequate directions for use in the treatment of vitamin C deficiency which was the purpose for which it was intended as claimed in the label statement "Provides therapeutic doses of ascorbic acid for the correction of vitamin C deficiency."

DISPOSITION: 4-25-60. McKesson & Robbins, Inc., claimant, having consented to the entry of a decree without admitting the alleged misbranding, judgment of condemnation was entered and the court ordered that the product be released under bond for relabeling.

**6170. Cough medicine.** (F.D.C. No. 44230. S. No. 64-428 P.)

QUANTITY: 415 cases, 12 2-oz. btl. each, at Stamford, Conn.

SHIPPED: Between 2-16-59 and 3-11-59, from Long Island City, N.Y., by Denver Chemical Mfg. Co.

LABEL IN PART: (Btl) "Dr. Hand's Cough Medicine For Children For Coughs Due to Colds Each 30 cc contains: Hyoscyamus alkaloids .06 mg. Sodium Bromide USP .4 gm. Sanguinaria Fluidextract, Ipecac Fluidextract USP, Tolu Balsam Tincture USP, Menthol USP, Alcohol 4% \* \* \* Hand Medicine Co., Inc., New York, N.Y. Successors to D. B. Hand, M.D. \* \* \* 60 cc."

ACCOMPANYING LABELING: (Leaflet in ctn.) "Today's Answer to Children's Coughs Due to Colds Dr. Hand's Cough Medicine for Children."

LIBELED: 2-10-60, Dist. Conn.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for coughs due to virus and bacterial infections; tonsillitis; pharyngitis; laryngitis; tracheitis; and bronchitis; 502(f) (1)—the labeling of the article failed to bear adequate directions for use since it provided for unsupervised administration to infants and small children; and 502(f) (2)—the article failed to bear adequate warnings against use since the labeling failed to warn that the article should not be taken by persons with a high fever or persistent cough unless directed by a physician; that the article was not to be used by elderly persons or by children under six (6) years of age unless directed by a physician; that the recommended dosage should not be exceeded; that if dryness of the mouth occurred dosage should be decreased; and that one should discontinue use if rapid pulse, dizziness, or blurring of vision occurred.

DISPOSITION: 6-17-60. Default—destruction.

**6171. Australian Tea Tree Oil and herbal preparations.** (F.D.C. No. 44189. S. Nos. 90-802 P, 90-816/9 P.)

QUANTITY: 35 2-oz. btl. of *Australian Tea Tree Oil*; 11 3-oz. boxes and 1 bulk bag containing about 4,800 tablets, and 15 100-tablet btl. of *Compound Herb Tea Formula No. KA 13*, 22 4-oz. boxes and 1 bag containing about 9,800 tablets of *Compound Herb Tea Formula No. SL 15*, at Quincy, Mass., in possession of Puregrade Health Products, Inc.

SHIPPED: Between 4-17-59 and 9-9-59, from outside the State of Massachusetts.

LABEL IN PART: (Btl.) "Australian Tea Tree Oil (100%) For use as a Mild Antiseptic \* \* \* Distributed by Puregrade Health Products, Inc., 25 School Street, Quincy 69, Mass."; (box) "Compound Herb Tea Formula No. KA 13 Puregrade Health Products, Inc., Quincy 69, Mass. \* \* \* Active Ingredients: Eucalyptus Leaves, Lemon Balm Herb, Holly Leaves, Red Poppy Flowers,



Linden Flowers and Leaves, Licorice Root, Buckthorn Bark, Calendula Petals"; (btl.) "Herbal Tablet Formula KA 13 Prepared for Pure Grade Health Products, Inc. \* \* \* Caution \* \* \* Active Ingredients \* \* \* Directions"; (box) "Compound Herb Tea Formula No. SL 15 Puregrade Health Products, Inc., Quincy 69, Mass. Net Weight: 4 Oz. \* \* \* Active Ingredients: Senna Leaves, Fennel Seed, Buckthorn Bark, Licorice Root, Bladderwrack, Sweet Orange Peel, Matte, Malva Flowers, Cyani Petals, Mexican Saffron, Calendula Petals. \* \* \*"; (bulk bag) "Formula #SL 15 Contents: Senna Leaves, Buckthorn Bark, Bladderwrack, Fennel Seed, Licorice Root, Sweet Orange Peel, Matte. Directions \* \* \* Use: Laxative \* \* \* Caution."

**ACCOMPANYING LABELING:** Leaflets entitled "Australian Tea Tree Oil" and "Medicinal Teas and tablets."

**RESULTS OF INVESTIGATION:** The articles were repacked and relabeled by the dealer from bulk stock shipped as described above. The leaflets were printed locally for the dealer.

**LICENSED:** 1-18-60, Dist. Mass.

**CHARGE:** 502(a)—while held for sale, the labeling which accompanied the Tea Tree Oil, namely, the leaflet entitled "Australian Tea Tree Oil," contained false and misleading representations that the Tea Tree Oil was an adequate and effective treatment for healing fungus infections; perionychia; empyema; gynaecological conditions; psoriasis; impetigo; pediculosis; tinea; ringworm; athlete's foot; acute nasopharyngitis; catarrh; thrush; stomatitis; tonsillitis; sore throat; mouth ulcers; insect bites; itches; sores; wounds and abrasions; pimples; boils; carbuncles; and pyorrhea; killing typhoid bacillus; curing colitis; coryza; exposed ulcers; halitosis; gingivitis; pruritic acne; and conjunctivitis; and preventing colds; and the leaflets entitled "Medicinal Teas and Tablets" contained false and misleading representations that the Formula No. KA 13 was an adequate and effective treatment for the temporary and palliative relief of the paroxysms of asthma; and that the Formula No. SL 15 was adequate and effective for controlling weight by eliminating body wastes; and 502(f) (2)—the labeling of the Formula No. SL 15 failed to bear adequate warning against prolonged use, or use in those pathological conditions where its use may be dangerous to health.

**DISPOSITION:** 3-21-60. Default—destruction.

**6172. Various drugs.** (F.D.C. No. 44202. S. Nos. 72-946/53 P.)

**QUANTITY:** 2,000 individually cartoned tubes, 10 tablets each, of *Aspi-Quinine*, 8,500 individually cartoned tubes, 30 tablets each, of *Citrovit*, 800 individually cartoned btl., 40 tablets each, of *Ceferbios Metallic Therapy*, 2,000 individually cartoned btl. of *Bitter Tonic Giuliani*, 3,000 individually cartoned btl., 20 tablets each, of *Giuliani Bitter Laxative*, 250 individually cartoned 150-cc. btl. of *Gastro-Zyme*, 80 individually cartoned boxes of *Coffosil*, 80 boxes, 40 tablets each, of *Zimotris Composition*, at New York, N.Y., in possession of Italian Drugs Importing Co.

**SHIPPED:** The *Gastro-Zyme* was imported sometime prior to January 1957, and the other articles between 6-21-57 and 7-23-59, from Italy.

**LABEL IN PART:** (Ctn. & tube) "Aspi-Quinine Each Tab. Con.; Aspirin 0.40 Gm.—Quin. Hydrobromide 0.05 Gm. Indications \* \* \* Warning"; "Citrovit \* \* \* Citro-Alkaline Tablets with Vitamin C Gastric Antacid Dosage:"; (ctn. & btl.) "Ceferbios Metallic Therapy With Vit. B<sub>12</sub> and Folic Acid \* \* \* Each

Tablet Contains: Iron Salt of Inositol Hexaphosphoric Acid 0.20 Gm. Copper Salt of Inositol Hexaphosphoric Acid 0.004 Gm. Manganese Salt of Inositol Hexaphosphoric Acid 0.0065 Gm. Cobalt Salt of Inositol Hexaphosphoric Acid 0.00075 Gm. Folic Acid 0.0005 Gm. Vitamin B<sub>12</sub> 2 Mcgm. Aromatized Sugar q.s. \* \* \* Control No. 26159 Lot No. 513"; "Bitter Tonic Giuliani Each 1 cc. contains: Aromatic Ext. Calamus 25 mg. Tinc. Gentian 40 mg. Aqueous Tinc. Boldus 5 mg.—Sodium Acid Carbonate 5 mg.—Glycerine 50 mg.—Distilled Water 250 mg.—Aromatic Excipients 95% Alcohol 100 mg., Sugar 170 mg., Water 33 mg., 2 drops Mint Essence, 2 drops Anise Essence, 2 drops Cinnamon Essence, 625 mg. Alcohol 14% by volume"; "Giuliani Bitter Laxative \* \* \* Each Tablet contains: Extract Rhubarb 20 Mg.—Extract Cascara Sagrada 20 Mg.—Phenolphthalein 60 Mg.—Excipients and Sugar Q. S."; "Gastro-Zyme I.S.M. Oral Each 100 cc. contains: Extract of fresh gastric mucous of swine 15 Gms. Extract of fresh gastric muscle of swine 10 gms. Peptones from alimentary proteins 7 Gms. Combined in a pleasantly flavored vehicle consisting of glycerin, water and flavor. \* \* \* Control No. 378"; "Coffosil \* \* \* Each 100 grams contains: Thymus Nepeta Extract 2 gm. Potassium Sulfo-guaiaacolate 2-5 gm. Sodium Glycerophosphate 1 gm. Sodium Formate 3 gm. Glyceric Syrup Solution Q.S. 100 gm. Indications \* \* \* Suggested Dosage \* \* \* Warning \* \* \* Control No. 593105"; and (box) Zimotris Composition: Each tablet contains: Pepsin 1:2500-50 mg. (Equivalent to 300 Units) Trypsin 1: 150-25 mg. (Equivalent to 350 Units) Lipase (F.U.) 25 mg.; Amylase 1: 50-50 mg. Indications \* \* \* Dosage."

ACCOMPANYING LABELING: Leaflets entitled "Pharmaceutical Products of Exceptional Merit" and "Specialita' Medicinali Di Porvata Efficacia Curativa," "Giuliani Bitter Laxative Tablets," and "Gastro-Zyme I.S.M."

RESULTS OF INVESTIGATION: The leaflets entitled "Pharmaceutical Products of Exceptional Merit" and "Specialita' Medicina Di Porvata Efficacia Curativa" were printed locally for the dealer and used to promote sales of the articles.

LIBELED: 2-1-60, S. Dist. N.Y.

CHARGE: 502(a)—while held for sale, the labeling which accompanied the articles, namely, the leaflets entitled "Specialita' Medicinali Di Porvata Efficacia Curativa" and "Pharmaceutical Products" contained false and misleading representations that the *Aspi-Quinine* was an adequate and effective treatment for colds, influenza, neuralgia, and rheumatism; that the *Citrovit* was an adequate and effective treatment for conditions of the liver and intestines, would help to eliminate excess uric acid, correct digestive secretions and was an infallible remedy; that the *Cefebrios Metallic Therapy* was an adequate and effective treatment for the nervous system, for the tired feeling, and for all kinds of anemia; and would make one feel stronger in just a few days; that the *Bitter Tonic Giuliani* was an adequate and effective treatment for dizziness, headache, heartburn, constipation, loss of appetite, hyperacidity, nausea, eructations and other intestinal disturbances; that the *Giuliani Bitter Laxative* was an adequate and effective treatment for habitual constipation; that the *Coffosil* was an adequate and effective treatment for bronchial conditions, bronchial catarrh, sore throat, and laryngitis; and that the *Zimotris Composition* was an adequate and effective treatment for constipation, intestinal fermentation, digestive disturbances, and would eliminate gas, boils, skin eruptions, and arteriosclerosis; 502(b)—the *Citrovit* failed to bear a label contain-



ing (1) the name and place of business of the manufacturer, packer, or distributor and (2) an accurate statement of the quantity of contents; 502(e) (2)—the *Citrovit* was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient; and 502(f)—The labeling of the *Aspi-Quinine* and the *Giuliani Bitter Laxative* failed to bear (1) adequate directions for use and (2) (*Aspi-Quinine*) adequate warnings for the protection of the user and (*Giuliani Bitter Laxative*) a warning statement for phenolphthalein; 502(a)—when shipped and while held for sale, the labeling of the *Gastro-Zyme*, namely, the leaflet entitled "Gastro-Zyme I.S.M.," contained false and misleading representations that the article was an adequate and effective treatment for chronic (atrophic) gastritis; gastric achylia; dyspepsia in anemic convalescent and aged subjects, infants and over-worked people; gastric neuroses; senile gastric hypotonia and hypochylia; and acute and chronic gastric catarrh.

DISPOSITION: 3-1-60. Consent—claimed by Italian Drugs Importing Co., Inc., New York, N.Y., and relabeled.

**6173. Desitin Rectal Ointment.** (F.D.C. No. 44227. S. No. 67-957 P.)

QUANTITY: 60 individually cartoned tubes at Philadelphia, Pa.

SHIPPED: 12-23-59, from Providence, R.I., by Desitin Chemical Co.

LABEL IN PART: (Ctn. and tube) "1½ Ounces Rectal Desitin Ointment Contains: Zinc Oxide, Norwegian Cod Liver Oil, Lanolin, Talcum, Sodium Lauryl Sulfate, Petrolatum qs. Manufactured by Desitin Chemical Company Providence, R.I."

ACCOMPANYING LABELING: Leaflet in carton entitled "Why New Rectal Desitin Ointment is a superior therapy."

LIBELED: 2-10-60, E. Dist. Pa.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for hemorrhoids (internal and external), anorectal conditions; pruritus ani; fissures; cryptitis; papillitis; proctitis; perianal dermatitis; and wounds resulting from cryptectomy; proctotomy; fissurectomy; and fistulectomy; and 502(f) (2)—the labeling of the article failed to warn that in case of rectal bleeding a physician should be consulted immediately.

DISPOSITION: 3-9-60. Default—destruction.

**6174. Niagara Cyclo-Massage devices.** (F.D.C. No. 43175. S. No. 16-283 P.)

QUANTITY: 1 glide-out sofa, 2 chaise lounges, 6 thermopads, 22 hand units, 7 all-purpose cushions, 2 #100 provincial chairs, 1 #200 queen chair, 3 #300 king chairs, 3 #400 standard chairs, 1 foam rubber mattress, 1 3-way professional table, 2 executive cushions, 22 sets consisting of thermopads and hand units, at Indianapolis, Ind., in possession of Niagara Distributors, Inc., and Kittle's Niagara Dealers, Inc.

SHIPPED: Between January 1956 and 4-28-59, from Adamsville, Pa.

LIBELED: 6-22-59, S. Dist. Ind.

CHARGE: 502(f) (1)—while held for sale, the labeling failed to bear adequate directions for use for the purposes for which it was intended, namely, in the treatment of Buerger's disease, wrinkles, crow's feet and bagginess under the chin, skin cancer, cerebral palsy in children, nerve interference, flushing out toxic poisons in the bloodstream, arthritis, bursitis, sinus attacks, high blood pressure, constipation, defective eyesight and hearing, paralysis and blindness



caused by multiple sclerosis, hemorrhoids, asthma attacks, heartburn, allergies, earache, sore throat, corns and callouses on feet, pimples, cancerous conditions, and reducing and gaining weight, which were the purposes for which the articles were offered orally by Lillian Acker, a saleslady on the dealer's premises.

**DISPOSITION:** 1-9-60. Default—1 all-purpose cushion, 1 #300 king chair, 5 sets consisting of thermopads and hand units, and 1 hand unit were ordered delivered to the Food and Drug Administration; 2 chaise lounges, 2 #100 provincial chairs, 2 #300 king chairs, 2 #400 standard chairs, and 1 foam rubber mattress were ordered delivered to a charitable institution for use as ordinary furniture after first removing and destroying the control unit in each device so as to render it inoperable for heat or vibrating purposes. The remainder of the articles were destroyed.

## DRUGS AND DEVICE ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

### DRUGS FOR HUMAN USE

#### 6175. Various drugs. (Inj. No. 350.)

**COMPLAINT FOR INJUNCTION FILED:** 1-23-59, N. Dist. Ill., against Hallmark Laboratories, Inc., a corporation, Custom Chemical Laboratories, a partnership, John Korabik, president of the corporation, Chicago, Ill., and Otto K. Benca, treasurer of the corporation and partner in the partnership, Cicero, Ill.

**CHARGE:** The complaint alleged that the defendants were engaged in manufacturing, preparing, packing, labeling, selling, and introducing and delivering for introduction into interstate commerce, various drugs which were adulterated and misbranded as follows:

501(b)—a number of such drugs purported to be drugs the names of which are recognized in the United States Pharmacopeia and the strength of the drugs differed from, or their quality or purity fell below, the standards set forth in such compendium;

501(c)—the strength of a number of such drugs differed from, or their quality fell below, that which they purported and were represented to possess;

502(a)—the labeling of a number of such drugs bore false and misleading statements with respect to the nature and quantity of the ingredients contained in the drugs;

502(e) (2)—a number of such drugs were not designated solely by a name recognized in an official compendium, were fabricated from two or more ingredients, and their labels failed to bear the common or usual name of each active ingredient; and

502(g)—a number of such drugs purported to be drugs the names of which are recognized in the United States Pharmacopeia and they were not labeled as prescribed by such compendium.

It was alleged also that the defendants were causing to be introduced and delivered for introduction into interstate commerce, contrary to the provisions of Section 505(a), new drugs which did not have effective new drug applications on file.

It was alleged further that, in the manufacturing, packaging, selling and distribution of the drugs, essentially the following methods were used:

(a) Hallmark Laboratories, Inc., purchased raw materials from various sources and furnished them to Custom Chemical Laboratories; (b)

Custom Chemical Laboratories manufactured bulk solutions of drugs for parenteral injection from said raw materials without making assays either of said raw materials or the prepared bulk solutions made from said raw materials; and

(c) the defendants then caused the bulk solutions to be transported to another manufacturer who repackaged the bulk solutions into either 10- or 30-cc. vials; that said 10- or 30-cc. vials were then returned to the premises of Hallmark Laboratories, Inc., where they were labeled and stored and from where they were distributed in interstate commerce.

The complaint alleged further that the adulterated and misbranded condition of said drugs resulted from deficiencies in the ingredients of the drugs; the presence in the drugs of ingredients in amounts in excess of those declared on the labels; the presence in the drugs of ingredients other than given on the labels; or the presence in the drugs of foreign matter, due either to inadequate manufacturing facilities, lack of identification control, lack of adequate analyses and formulas, lack of qualified personnel, or lack of other precautions essential to the compounding of potent drugs. For example, the 10-cc. vials of *Dexalamine ampuls* contained methapyrilene hydrochloride instead of pyranisamine maleate the ingredient given on the label, and contained racemic amphetamine in the amount of 3.7 milligrams rather than 2 milligrams of dextro-amphetamine sulfate; the *Solution of Vitamin B<sub>12</sub> (Cyanocobalamin U.S.P.)* vials, the *Vitamin B<sub>12</sub> (Cyanocobalamin U.S.P.) In Water For Injection* vials, and the vials of *Vitamin B<sub>12</sub> Crystalline U.S.P. 1000 Micrograms per cc. in Isotonic Sod. Chloride Soln. with 2% Benzyl Alcohol* all contained a substantial amount of unidentified dissolved material not permitted by the United States Pharmacopoeia monograph for *cyanocobalamin injection*; the 30-cc. vials of *Water For Injection U.S.P.* contained ½ percent of phenol, an added preservative, and its label failed to reveal that fact and the amount present as required in the United States Pharmacopoeia monograph for *Water For Injection*; the *Liver Injection U.S.P. (Beef)* contained more than 50 percent of the amount of cyanocobalamin shown on the label; the vials of *Sterile Progesterone U.S.P.* contained viable microorganisms and were not sterile; the *B-Complex with Vitamin B<sub>12</sub>* contained approximately 140 percent of the declared amount of riboflavin and was approximately 66 percent deficient in vitamin B<sub>12</sub>; and the *Liver-Folic Acid-B<sub>12</sub>* was approximately 66 percent deficient in vitamin B<sub>12</sub>.

It was alleged further that defendants were well aware that their activities violated the Act; that inspections were made of Hallmark Laboratories, Inc., in 1957 and 1958, and of Custom Chemical Laboratories in 1957, at which times the defendants were informed of the inadequacies encountered; that defendants were further warned by seizures of their vitamin B<sub>12</sub> for injection, and by hearings pursuant to Section 305 of the Act; and that despite such warnings, the defendants continued to introduce and cause to be introduced and deliver and cause to be delivered for introduction into interstate commerce, adulterated and misbranded drugs.

**DISPOSITION:** On 2-6-59, the defendants having consented, a temporary injunction was entered. The temporary injunction was subsequently extended by consent and on 2-15-60, at which time it was revised, it was extended until 2-15-62. The revised temporary injunction enjoined and restrained the defendants from directly or indirectly introducing or causing to be introduced or delivering or causing to be delivered for introduction into interstate commerce, drugs such as those named above or any similar drugs that are

adulterated or misbranded as alleged in the complaint or are new drugs which do not have an effective new drug application on file.

The temporary injunction further enjoined the defendants from directly or indirectly causing to be introduced or delivered for introduction into interstate commerce, any drug manufactured, processed, relabeled, or repacked by them unless and until:

- (a) Sufficient qualified and experienced personnel, including supervisory personnel are employed in the plant to properly operate it;
- (b) A properly qualified pharmaceutical chemist is employed to make sufficient analyses of each batch of finished drug to insure that it conforms to the labeling under which it is to be shipped, and to the requirements of the National Formulary or United States Pharmacopoeia or other standard which may be applicable. Lacking this, a representative sample of each finished batch of drugs is submitted to a reliable established outside laboratory for examination and the results of such examination are received prior to shipment;
- (c) A system of properly identifying and storing raw materials as they are received at the plant is instituted;
- (d) Batches of drugs in preparation are not manipulated in an improper manner resulting in unwarranted shortages or overages in the final yield;
- (e) Sampling of finished tablets, injectionables, and all other finished products is done in a representative manner to insure the taking of a representative, adequate sample;
- (f) Capsules are assayed in finished form rather than in earlier stages of manufacture;
- (g) The practice of shipping finished batches of drugs prior to analysis or without analysis is discontinued;
- (h) The distribution of new drugs without effective new drug applications is discontinued;
- (i) At least one qualified person in the plant has sufficient information concerning the new drugs shipped from this plant to eliminate confusions and violations;
- (j) Adequate samples of incoming raw materials are taken and appropriate analyses of these samples made;
- (k) Preparation of manufacturing records and forms is done with such clarity, care and completeness that each lot or batch of drugs manufactured, processed, relabeled, or repacked is so identified that the complete manufacturing, packing, and labeling history and control examination reports are readily available and so as to eliminate mistakes and confusion;
- (l) Each batch or lot of drugs manufactured, processed, relabeled or repacked is properly identified at all times and during all stages of said manufacturing, processing, relabeling, or repacking;
- (m) Operations involving the weighing out of raw materials and the preparation of formulas and application of labeling are checked by another qualified party in addition to the employee originally performing such duties;
- (n) Returned goods are recorded, handled, stored, and again disposed of in a manner which will eliminate uncertainty, confusion, and the possibility of mistakes;
- (o) Samples of each lot of raw materials and each batch or lot of drugs manufactured, processed, relabeled, or repacked by them are taken and



retained for the time reasonably necessary for the distribution and use of drugs distributed; and

(p) Representatives of the Food and Drug Administration of the Department of Health, Education, and Welfare are given free access to all records and controls pertaining to (1) the receipt of all raw materials or lots of drugs for manufacturing, processing, repacking, or relabeling; (2) the manufacturing, processing, repacking, or relabeling of all lots or batches of drugs; and (3) the distribution of all batches or lots of drugs whether interstate or intrastate, including, but not limited to, the records necessary to establish that adequate control systems have been installed embodying all of the herein listed safeguards for interstate commerce considered necessary to good pharmaceutical manufacturing practice.

**6176. Conjugated estrogen powder.** (F.D.C. No. 43181. S. No. 11-062 P.)

QUANTITY: 8 cans, each containing 2 kilograms, at Buffalo, N.Y.

SHIPPED: 5-2-58, from Montreal, Canada, by Steroid Laboratories, Ltd.

LABEL IN PART: "Product of Steroid Laboratories Limited Box 247 Montreal Canada 2 kilograms Conjugated Estrogens (Equine) Powder Each Gram Contains 17.1 Mg. Estrogens (as Conjugates)—Control No. 91497."

RESULTS OF INVESTIGATION: Analysis showed that total estrogen content corresponded to not more than 14.7 mgs. of estrone per gram.

LIBELED: 6-6-59, W. Dist. N.Y.

CHARGE: 501(c)—when shipped and while held for sale, the strength of the article differed from that which it purported and was represented to possess; and 502(a)—the label statement "Each gram contains 17.1 Mg. Estrogens" was false and misleading since the article contained not more than 14.7 mg. of estrone per gram.

DISPOSITION: 2-8-60. Consent—claimed by Steroid Laboratories, Ltd., and relabeled.

**6177. Conjugated estrogen granules.** (F.D.C. No. 44054. S. No. 86-566 P.)

QUANTITY: 4 cans containing a total of about 6,176 grams of estrogen (equine) granules at Buffalo, N.Y.

SHIPPED: 9-1-59, from Brooklyn, N.Y., by International Hormones, Inc., after having been imported during 1956, from Steroid Laboratories, Ltd., Montreal, Canada.

LABEL IN PART: (Can) "International Hormones, Inc. \* \* \* Brooklyn 1, N.Y. 1546 Grams Conjugated Estrogens (Equine) Granules 7.074 mg/gram Estrogens after Hydrolysis \* \* \* Control #79001."

RESULTS OF INVESTIGATION: Analysis showed the total estrogen content corresponded to not more than 4.61 mgs. of estrone per gram.

LIBELED: 2-4-60, W. Dist. N.Y.

CHARGE: 501(c)—when shipped and while held for sale, the strength of the article differed from that which it purported and was represented to possess; and 502(a)—the label statement "7.074 mg/gram" was false and misleading as applied to an article which contained 4.61 mgs. of estrone per gram.

DISPOSITION: 3-9-60. Default—destruction.

6178. Conjugated estrogen powder and conjugated estrogen granules. (F.D.C. No. 43915. S. Nos. 65-949/50 P, 65-960 P.)

QUANTITY: 2 cans, 500 grams each, and 3 cans, 2 kilograms each, of estrogen powder, and 7 cans of estrogen granules, at Buffalo, N.Y.

SHIPPED: Between July 1954 and 8-5-59, from Montreal, Canada, by Steroid Laboratories, Ltd.

LABEL IN PART: (Can) "Product of Steroid Laboratories Limited \* \* \* Montreal, Canada, 500 Grams [or "2 Kilograms"] Conjugated Estrogens (Equine) Powder \* \* \* Control No. 71302 [or "73730"]" or "1546 Grams Conjugated Estrogens (Equine) Granules. 5.67 mg/gram \* \* \* Control No. 87243."

RESULTS OF INVESTIGATION: Analysis showed that the total estrogen content corresponded to not more than (2 cans) 12.6 mgs., (3 cans) 11.2 mgs., and (7 cans) 4.7 mgs. of estrone per gram.

LIBELED: 11-17-59, W. Dist. N.Y.

CHARGE: 501(c)—when shipped and while held for sale, the strength of the article differed from that which it purported and was represented to possess; and 502(a)—the label statements of the articles (2 cans) "15.45 mgm/gm," (3 cans) "13.29 mgm/gm," and (7 cans) "5.67 mg/gram" were false and misleading.

DISPOSITION: 2-8-60. Consent—claimed by Steroid Laboratories, Ltd., Montreal, Canada; one can was destroyed and the remainder were relabeled.

6179. Vernalin (ophthalmic solution). (F.D.C. No. 43970. S. No. 69-722 P.)

QUANTITY: 70 8-oz. cartoned btls. at Trenton, N.J.

SHIPPED: 10-27-59, from Philadelphia, Pa., by Wall & Ochs, Inc.

LABEL IN PART: (Btl. & ctn.) "Vernalin (Improved) Contains: Sodium Carbonate Monohydrated (Active Ingredient) Camphor Water, Rose Water, Fluorescein Sodium (Diagnostic Agent) Chlorbutanol 0.5% as preservative \* \* \* Wall & Ochs \* \* \* Chestnut Street, Phila."

ACCOMPANYING LABELING: Circular entitled "Vernalin."

RESULTS OF INVESTIGATION: Examination showed that the article was contaminated with viable microorganisms.

LIBELED: 12-17-59, Dist. N.J.

CHARGE: 501(c)—when shipped, the quality and purity of the article fell below that which it purported to possess; and 502(a)—the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for all types of conjunctivitis.

DISPOSITION: 1-18-60. Default—destruction.

6180. Digitalis tablets. (F.D.C. No. 43926. S. Nos. 85-337/8 P.)

QUANTITY: 160,000 tablets in bulk drums and 48 1,000-tablet btls. at Edgewater, N.J.

SHIPPED: During May 1959, from New York, N.Y., by Excel Pharmacal Co.

LABEL IN PART: (Drum) "Tablets Digitalis Grains 1½ gr." and (btl.) "Excel 1,000 Tablets Digitalis 1½ Grains \* \* \* USP \* \* \* Manufactured by Excel Pharmacal Company, New York, N.Y."

RESULTS OF INVESTIGATION: Analysis showed that the digitalis potency of the article was less than the declared potency of 1½ grains per tablet. The tablets in the bottles had been repackaged by the dealer from the bulk drums shipped as described above.

**LIBELED:** 11-24-59, Dist. N.J.

**CHARGE:** 501(b)—when shipped, the strength of the article fell below the standard for digitalis tablets set forth in the United States Pharmacopeia; and 502(a)—the label statement "Digitalis 1½ Grains" was false and misleading.

**DISPOSITION:** 1-11-60. Default—destruction.

**6181. Canfield liquid lubricating jelly.** (F.D.C. No. 44043. S. No. 98-069 P.)

**QUANTITY:** 24 cases, each containing 12 16-oz. jars, at St. Louis, Mo.

**SHIPPED:** 10-12-59 and 11-18-59, from Minneapolis, Minn., by C. R. Canfield & Co.

**LABEL IN PART:** (Case) "No. 1921 Canfield Original Liquid Lubricating Jelly \* \* \* Sterile \* \* \* Ipse-Sterilis \* \* \* C. R. Canfield & Co. 2736-38 Lyndale Avenue, South, Minneapolis 8, Minnesota \* \* \* Control Number 4349."

**RESULTS OF INVESTIGATION:** Examination showed the article was contaminated with viable microorganisms.

**LIBELED:** 1-27-60, E. Dist. Mo.

**CHARGE:** 501(c)—when shipped, the quality and purity of the article fell below that which it purported and was represented to possess; and 502(a)—the label statement "Original Liquid Lubricating Jelly \* \* \* Sterile \* \* \* Ipse-Sterilis" was false and misleading as applied to an article that was not sterile.

**DISPOSITION:** 3-28-60. Default—destruction.

**6182. Prophylactics.** (F.D.C. No. 44356. S. No. 85-083 P.)

**QUANTITY:** 9 ctns., 50 gross boxes each, at Baltimore, Md.

**SHIPPED:** During the week of 2-1-60, from Hartville, Ohio, by Allied Latex Sales Co.

**LABEL IN PART:** "Liquid latex, sold for prevention of disease only, made in U.S.A., C-1-60A."

**RESULTS OF INVESTIGATION:** Examination showed that 1.5 percent of the article was defective in that it contained holes.

**LIBELED:** 2-26-60, Dist. Md.; amended 3-29-60.

**CHARGE:** 501(c)—when shipped, the quality of the article fell below that which it purported to possess; and 502(a)—the label statement "sold for prevention of disease only" was false and misleading as applied to an article containing holes.

**DISPOSITION:** 5-10-60. Default—destruction.

#### DRUG FOR VETERINARY USE

**6183. Wirthmore Coccidiosis Treatment.** (F.D.C. No. 44260. S. No. 91-065 P.)

**QUANTITY:** 20 100-lb. bags at Plainfield, Conn.

**SHIPPED:** 12-8-59, from Bridgewater, Mass., by Eastern Grain Co.

**LABEL IN PART:** (Bag) "Wirthmore Coccidiosis Treatment Ration 411 \* \* \* Active Drug Ingredient Sulfaquinoxaline .05% \* \* \* Manufactured for Wirthmore Feeds, Inc., Waltham, Mass."

**RESULTS OF INVESTIGATION:** Examination showed that the article contained approximately 0.027 percent of sulfaquinoxaline.

**LIBELED:** 3-4-60, Dist. Conn.



**CHARGE:** 501(c)—when shipped, the quality of the article fell below that which it purported and was represented to possess, namely, .05 percent sulfaquinoxaline; and 502(a)—the label statement "Sulfaquinoxaline .05%" was false and misleading.

**DISPOSITION:** 5-6-60. Default—delivered to a Federal institution for use as animal feed.

## DRUGS AND DEVICE ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

### DRUGS FOR HUMAN USE\*

**6184. Organic mineral salt.** (F.D.C. No. 43685. S. No. 35-469 P.)

**INFORMATION FILED:** 12-29-59, S. Dist. Calif., against Dr. E. H. Bronner & Associates, a partnership, Los Angeles, Calif., and Emanuel H. Bronner, partner.

**SHIPPED:** 3-14-58, from California to Pennsylvania.

**LABEL IN PART:** "Dr. Bronner's Organic Mineral Salt \* \* \* Stop tooth decay the edible way \* \* \* Mfg. & Fully Guaranteed by Dr. E. H. Bronner & Associates \* \* \* Escondido, Cal."

**ACCOMPANYING LABELING:** Leaflet entitled "Organic Mineral Salt & Bouillon."

**CHARGE:** 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article would be adequate and effective for the stopping of tooth decay.

**PLEA:** Guilty.

**DISPOSITION:** 3-21-60. Partnership—\$1,000 fine suspended; individual—1 year in prison suspended, and probation for 2 years.

**6185. Slim-Time reducing capsules.** (F.D.C. No. 44084. S. No. 86-633 P.)

**QUANTITY:** 360 30-capsule boxes and 720 14-capsule boxes at Buffalo, N.Y.

**SHIPPED:** 7-13-59, from Dallas, Tex., by Preston National Drug Co.

**LABEL IN PART:** (Box front) "Slim-Time Disintegrating Reducing Capsules Each Capsule Contains 75 mgm. Phenyl Propanolamine Hydrochloride in a special timed disintegration base that provides for prolonged effect for about 6 to 10 hours \* \* \* Distributed by Herculex Drug Co., Inc. Buffalo, New York."

**ACCOMPANYING LABELING:** Insert leaflet entitled "Eat What You Like, But."

**LIBELED:** 3-10-60, W. Dist. N.Y.

**CHARGE:** 502(a)—when shipped, the name and the labeling of the article contained false and misleading representations that the article was effective for reducing weight and for treatment of obesity without rigid diets.

**DISPOSITION:** 4-13-60. Default—destruction.

**6186. Vitamin E capsules.** (F.D.C. No. 44253. S. No. 77-340 P.)

**QUANTITY:** 203 100-capsule btls. at Seattle, Wash., in possession of Pay'n Save Drug.

**SHIPPED:** Between 7-30-59 and 12-4-59, from Portland, Oreg.

\*See also Nos. 6163, 6165, 6167, 6169-6173, 6175-6183.

**LABEL IN PART:** "Pioneer \* \* \* List No. 51 [or "53"] Vitamin 'E' \* \* \* Vitamin E capsules contain: d-alpha tocopheryl Acetate Conc. NF equivalent to 50 [or "100"] International Units Vitamin E."

**ACCOMPANYING LABELING:** Newspaper tear sheets from the Seattle Times, Wednesday, January 13, 1960.

**LIBELED:** 2-23-60, W. Dist. Wash.

**CHARGE:** 502(a)—while held for sale, the label statement "The Need for vitamin E in human nutrition has not been established" was false and misleading and the labeling which accompanied the article contained false and misleading representations that the article was adequate and effective for the prevention of problems during menopause and persistent skin ulcers.

**DISPOSITION:** 4-4-60. Default—destruction.

**6187. Blake geriatric formula.** (F.D.C. No. 44088. S. No. 96-386 P.)

**QUANTITY:** 90 individually cartoned 100-capsule btl. at Marshalltown, Iowa, in possession of Osco Drug.

**SHIPPED:** Between 1-11-59 and 1-16-59, from Allegan, Mich., by L. Perrigo Co.

**LABEL IN PART:** "Capsules Blake Hi-Potency Geriatric Formula Plus B-12, Blake Pharmacal Co., Allegan, Mich."

**ACCOMPANYING LABELING:** Newspaper tear sheets and placards reading in part "Blake Hi-Potency Geriatric Formula" and signs reading in part "Combat Colds! Build Resistance with Vitamins."

**LIBELED:** 3-15-60, S. Dist. Iowa.

**CHARGE:** 502(a)—when shipped and while held for sale, the name and the labeling which accompanied the article contained false and misleading representations that it was adequate and effective to promote health and vitality; prevent premature aging; maintain youthful pep, energy and spirit; and develop resistance to disease.

**DISPOSITION:** 4-14-60. Default—destruction.

**6188. Nasal inhalant.** (F.D.C. No. 44366. S. No. 90-965 P.)

**QUANTITY:** 282 counter cards, each containing 1 individually cartoned 30-cc. btl., at Boston, Mass.

**SHIPPED:** 1-25-60, from Trenton, N.J., by Astron Chemicals & Pharmaceuticals, Inc., New York, N.Y.

**LABEL IN PART:** (Ctn.) "Instantly Nasal Inhalant \* \* \* Ingredients: Alcohol 25%, Chloroform 9 min. per. fl. oz., Oil of camphor, Eucalyptol, Menthol, Camphor. Astron Chemicals and Pharmaceuticals, Inc. New York 18, N.Y."

**ACCOMPANYING LABELING:** Card entitled "Not a nose drop! Not a spray!" and leaflet in carton entitled "Instantly The Modern Nasal Decongestant."

**LIBELED:** 3-7-60, Dist. Mass.

**CHARGE:** 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for sinus congestion and nasal congestion due to colds, hay fever, and allergies.

**DISPOSITION:** 4-25-60. Default—destruction.

**6189. Dex-A-Diet tablets.** (F.D.C. No. 44074. S. No. 42-935 P.)

**QUANTITY:** 20 21-tablet btl. and 12 100-tablet btl. at Denver, Colo.

SHIPPED: 1-22-60, from Detroit, Mich., by Alpha Tablets Co.

LABEL IN PART: "Dex-A-Diet A True Appetite Depressant Packaged by O'Connor Bros. Drug Co. For Alpha Tablets Co., Detroit, Michigan \* \* \* Each Tablet Contains: Phenylpropanolamine Hydrochloride 25 Mg."

LIBELED: 2-29-60, Dist. Colo.

CHARGE: 502(a)—when shipped, the labeling which accompanied the article contained false and misleading representations that the article was adequate and effective as an appetite depressant and in the management and treatment of obesity.

DISPOSITION: 4-21-60. Default—destruction.

6190. Gelatin Slim capsules. (F.D.C. No. 44233. S. No. 93-168 P.)

QUANTITY: 7 30-capsule boxes, 11 90-capsule boxes, and 5 201-capsule boxes at Seattle, Wash.

SHIPPED: Between 7-27-59 and 10-28-59, from Santa Monica, Calif., by Gelatin Plus, Inc.

LABEL IN PART: (Insert label) "Ten Gr. Capsules Gelatin Slim A Dietary Supplement The modern aid to figure beauty Each capsule contains 445 mg. of pure high protein sugarless gelatin and 182 mg. of true citrus cellulose \* \* \* Distributed by Gelatin-Plus, Santa Monica, Calif."

ACCOMPANYING LABELING: Leaflet in box entitled "Gelatin Slim."

LIBELED: 2-10-60, W. Dist. Wash.

CHARGE: 502(a)—when shipped and while held for sale, the labeling of the article contained false and misleading representations that it was adequate and effective for curbing the appetite; for weight reduction without rigid diets; that it would build firm healthy tissues and help one to look and feel younger and more attractive; and that use of the article would produce "figure beauty."

DISPOSITION: 4-4-60. Default—destruction.

6191. Slippery elm food, dandelion essence, and roasted dandelion root. (F.D.C. No. 44224. S. Nos. 42-288 P, 42-292/3 P.)

QUANTITY: 9 1-lb. tins of *slippery elm food*, 48 4-oz. btls. and 35 8-oz. btls. of *dandelion essence*, and 42 ¼-lb. tins and 13 ½-lb. tins of *roasted dandelion root*, at Seattle, Wash.

SHIPPED: Between 7-18-59 and December 1959, from Covington, Ky., by Dandelions Unlimited (Irene E. Barbasch).

LABEL IN PART: "Thompson's Slippery Elm Food \* \* \* Contains: Precooked Wheaten Flour, Powdered Slippery Elm Bark and Sugar Unmalted Sole Proprietors Potter & Clarke, Ltd."; "Prepared from pure Dandelion Root Thompson's Dandelion Essence \* \* \* Sole Proprietors Potter & Clarke, Ltd. \* \* \* Sole Importer and Distributor for U.S.A. Irene E. Barbasch \* \* \* Covington, Kentucky"; and "Thompson's Roasted Dandelion Root \* \* \* Product of England \* \* \* Irene E. Barbasch \* \* \* Covington, Kentucky."

ACCOMPANYING LABELING: Leaflets entitled "The Story of Thompson's Slippery Elm Food and Its Value to You" and "Dandelions & You."

LIBELED: 2-5-60, W. Dist. Wash.

CHARGE: 502(a)—when shipped, the accompanying labeling of the articles contained false and misleading representations that the *slippery elm food*



was an adequate and effective treatment for inducing sleep; managing ulcerative conditions and mucous colitis; providing healing properties; restoring and maintaining health; and overcoming frayed nerves; digestive disorders; inflammation, dysentery, diarrhea, and urinary troubles; and that the *dandelion essence* and *roasted dandelion root* were an adequate and effective treatment for stimulating the liver and kidneys to improve elimination; cleansing the bloodstream, to aid in eliminating toxins and other impurities from the system; and for making eyes and complexion clearer and for removing pimples.

DISPOSITION: 5-31-60. Default—destruction.

**6192. Kanker Komfort.** (F.D.C. No. 44108. S. No. 28-707 R.)

QUANTITY: 10 1-gal. glass jugs and 249 vials at Duluth, Minn., in possession of Oral Prophylactic Association, Inc.

SHIPPED: 8-24-59, from Lafayette, Ind.

LABEL IN PART: (Jug) "Control Number 29831 Date 8-6-59 Prepared for Oral Prophylactic Ass'n., Duluth, Minnesota \* \* \* Each Fluid Ounce Represents Pectin 11½ grs. Bismuth Sodium Tartrate 7½ grs. Lafayette, Indiana" and (vial) "Kanker Komfort for Cankers, cold sores, denture abrasions, minor mouth lacerations, Cont. 3 Fluid Drams \* \* \* Manufactured for Oral Prophylactic Association, Inc., Duluth, Minn."

RESULTS OF INVESTIGATION: The article in the vials was repacked and relabeled from the jugs which had been shipped as described above.

LIBELED: 3-30-60. Dist. Minn.

CHARGE: 502(a)—while held for sale, the name and the label of the article contained false and misleading representations that it was an adequate and effective treatment for cankers, cold sores, denture abrasions, and minor mouth lacerations.

DISPOSITION: 5-6-60. Consent—claimed by Oral Prophylactic Association, Inc., and relabeled.

**6193. Stimavite Tastitabs.** (F.D.C. No. 44380. S. No. 91-021 P.)

QUANTITY: 53 individually cartoned btls. at Taunton, Mass.

SHIPPED: Prior to March 1957, from Chicago, Ill., by J. B. Roerig & Co., Div. Chas. Pfizer & Co., Inc.

LABEL IN PART: (Btl. & ctn.) "No. 2841 Stimavite Tastitabs \* \* \* J. B. Roerig and Company, Chicago 11, Illinois, Division Chas. Pfizer & Co., Inc. Each tablet contains: Vitamin B-12 20 mcg. Vitamin B-6 3 mg. Vitamin B-1 10 mg. Vitamin C (as sodium ascorbate) 25 mg. Lysine 15 mg. Lot No. 64108."

LIBELED: 3-24-60, Dist. Mass.

CHARGE: 502(a)—when shipped, the label statement "Appetite stimulant for children containing Lysine to promote proper growth" was false and misleading since the article was not adequate and effective for such purposes.

The libel alleged also that a number of articles were adulterated and misbranded under the provisions of the law applicable to foods as reported in notices of judgment on foods.

DISPOSITION: 5-16-60. Default—destruction.

**6194. Vege-Whey.** (F.D.C. No. 44378. S. No. 93-225 P.)

QUANTITY: 115 16-oz. jars, 14 3-lb. jars, and 5 5-lb. jars, at Seattle, Wash.

SHIPPED: Between 1-27-59 and 11-9-59, from Los Angeles, Calif., by Vegetrates Co.

LABEL IN PART: (Jar) "Swiss Type Vege-Whey \* \* \* Dairy-Fresh Whey Dehydrated to make a Rich, Concentrated, Wholesome Beverage Made Only From Certified Raw Milk. Analysis: Lactose: Approximately 70%, a nutritious, nourishing, easily-digested sugar. Protein: Approximately 12%, Contains those proteins natural to milk. Vege-Whey: Contains easily assimilable calcium and phosphorus from milk. \* \* \* Distributed by Vegetrates Company, Los Angeles, Calif."

ACCOMPANYING LABELING: Leaflets entitled "Avoid Intestinal Putrefaction" and placards reading in part "Are You Troubled With Intestinal Toxemia? Swiss Type Vege-Whey."

LIBELED: 3-21-60, W. Dist. Wash.

CHARGE: 502(a)—the labeling accompanying the article, when shipped, contained false and misleading representations that it was an adequate and effective treatment for intestinal toxemia, intestinal disorders due to putrefactive flora, and to combat stagnation of the intestines, retard putrefaction, and promote free, natural laxation.

DISPOSITION: 5-31-60. Default—destruction.

6195. VitaWell Anti-Cholesterol tablets. (F.D.C. No. 44388. S. No. 80-078 P.)

QUANTITY: 237 100-tablet btls. and 35 250-tablet btls. at Harbert, Mich.

SHIPPED: November 1958, from Inwood, N.Y., by Barrows Chemical Co., Inc.

LABEL IN PART: (Btl.) "VitaWell Natural Organic Anti Cholesterol Tablets A rich dietary supplement providing the natural occurring lipotropic factors in high potencies as occurring in soy-bean lecithin, coupled with rice bran concentrate, unsaturated fatty acids, and vitamin B-12 activity. Daily Dosage of Six Tablets Contains: Soy Bean Lecithin 1200 mg. Providing: Choline Phosphatidyl 400 mg. Providing: Inositol Containing Phosphatides 400 mg. Rice Bran Concentrate 120 mg. Unsaturated Fatty Acids (Principally Linoleic) 180 mg. Vitamin B<sub>12</sub> Activity (cobalamin concentrate) 4.5 mcg. Distributed by VitaWell Products Co., Harbert, Mich."

ACCOMPANYING LABELING: Catalogs entitled "Catalog of Vita Well Vitamins" which were printed on order of VitaWell Products Co.

LIBELED: 3-23-60, W. Dist. Mich.

CHARGE: 502(a)—when shipped and while held for sale, the name of the article "Anti-Cholesterol Tablets," and statements in its labeling, namely, bottle label and catalog entitled "Catalog of Vita Well Vitamins," contained false and misleading representations and suggestions that the article was adequate and effective for the prevention of the accumulation of cholesterol in the blood vessels; heart disease; hardening of the arteries; clogging of blood vessels; and strokes.

DISPOSITION: 5-6-60. Default—destruction.

6196. Arman's Nail-Kare Gelatin capsules, Arman's Kurbatine Chewing Gum tablets, and Arman's Stoma-Kons tablets. (F.D.C. No. 43542. S. Nos. 22-523/5 P.)

QUANTITY: 512 36-capsule btls. of Arman's Nail-Kare, 519 20-tablet btls. of Arman's Kurbatine Chewing Gum, and 358 50-tablet btls. of Arman's Stoma-Kons, at Omaha, Nebr., in possession of Arman Drug Co., Inc.

**SHIPPED:** Between 2-4-59 and 3-14-59, from Long Island City, N.Y.

**LABEL IN PART:** (Btl.) "Arman's Nail-Kare Gelatin Capsules \* \* \* Each Capsule contains 10 Grains of Pure Gelatin Containing Natural Amino Acids without Sugar Plus Added Calcium (As Dicalcium Phosphate) Directions: \* \* \* For use as a dietary supplement to provide protein; \* \* \* Beauty Aid: As a supplementary nourishment \* \* \* Arman Drug Co., Inc., Dist., Omaha, Nebr.," "Arman's Kurbatine Chewing Gum Tablets An Appetite Suppressant \* \* \* Each Chewing Gum Tablet Contains: Phenylpropanolamine Hydrochloride 25 Mg. Arman Drug Co. Dist. Omaha, Nebr.," and "Arman's Stoma-Kons \* \* \* Arman Drug Co., Inc., Dist. Omaha, Nebr. Each Tablet Contains: FMA-11 (Aluminum Hydroxide-Magnesium Carbonate, Co-Precipitate) 10 Grains."

**RESULTS OF INVESTIGATION:** The articles were repacked into bottles and relabeled from bulk stock shipped as described above.

**LIBELED:** 9-18-59, Dist. Nebr.

**CHARGE:** 502(a)—while held for sale, the labeling of the articles contained false and misleading representations that the articles were an adequate and effective treatment for (Nail-Kare) curbing appetite, reducing weight, and producing lovelier hair and skin; (Kurbatine) for depressing the appetite, reducing and controlling weight; and (Stoma-Kons) for peptic ulcers.

**DISPOSITION:** 5-5-60. Consent—destruction.

**6197. Healthbank Formula 2 capsules.** (F.D.C. No. 44246. S. No. 71-855 P.)

**QUANTITY:** 129 90-capsule btls. at St. Petersburg, Fla., in possession of Healthbank, Inc.

**SHIPPED:** 11-5-59, from Worcester, Mass.

**LABEL IN PART:** "Healthbank Formula 2 \* \* \* Distributed by Healthbank, Inc., St. Petersburg, Florida \* \* \* Each capsule contains 3 minims cold processed wheat germ oil with vegetable oil diluent \* \* \* 2028."

**ACCOMPANYING LABELING:** Circulars entitled "Dear Friend" and leaflets entitled "An Important Message About Your Heart."

**LIBELED:** 2-17-60, S. Dist. Fla.

**CHARGE:** 502(a)—the labeling accompanying the article, while held for sale, contained false and misleading representations that the article was adequate and effective for the prevention and treatment of heart disease and heart trouble; that it would help the heart action; that it would break down cholesterol in the arteries; that it would give one more stamina, vigor, endurance, and add many years to one's life; that the unsaturated fatty acids were necessary for life, health, and reproduction of humans and animals; and that it would stimulate the sex vitality of livestock.

**DISPOSITION:** 6-20-60. Default—a portion of the article and its labeling was delivered to the Food and Drug Administration and the remainder was destroyed.

**6198. Allenite vibrator cushion.** (F.D.C. No. 44079. S. No. 29-601 R.)

**QUANTITY:** 127 pillows in plastic bags at Minneapolis, Minn.

**SHIPPED:** 1-5-60 and 1-14-60, from Chicago, Ill., by Allenite Mfg. Co.

**ACCOMPANYING LABELING:** (Leaflet in bag) "Allenite Vibrator Cushion New Electric Massage Pillow \* \* \* Allenite Manufacturing Company \* \* \* Chicago 47 Illinois."



**RESULTS OF INVESTIGATION:** The article was a pillow-shaped, padded, cloth-covered device containing an electric motor capable of providing some vibration.

**LIBELED:** 3-9-60, Dist. Minn.

**CHARGE:** 502(a)—when shipped, the labeling which accompanied the article contained false and misleading representations that the article was an adequate and effective treatment for easing nervous tension; relieving aching back; reducing thighs; and aid in reducing.

**DISPOSITION:** 4-29-60. Default—3 pillows were delivered to the Food and Drug Administration and the remainder were destroyed.

#### DRUGS FOR VETERINARY USE

**6199. Kamala Compound Supplement.** (F.D.C. No. 43322. S. No. 45-635 P.)

**QUANTITY:** 8 25-lb. drums and 5 100-lb. drums at Denver, Colo.

**SHIPPED:** 4-8-59, from Omaha, Nebr., by Corn States Laboratories, Inc.

**TABLE IN PART:** "Kamala Compound Supplement Kamala, Tobacco, Iron, Sulphate, Castor Oil and Active Dry Yeast (in a vegetable protein base) for all livestock and poultry. To be mixed with grains, mash, slop or with salt in self-feeders \* \* \* manufactured by Vitamineral Products Company Peoria \* \* \* Illinois."

**ACCOMPANYING LABELING:** Pamphlet entitled "Vitamineral Products Company Where a Mixture of Kamala, Tobacco, Iron Sulphate, Castor Oil and Active Dry Yeast (in a vegetable protein base) is specified by veterinarians \* \* \* Directions for feeding."

**LIBELED:** 7-28-59, Dist. Colo.

**CHARGE:** 502(a)—the labeling accompanying the article, when shipped, contained false and misleading representations that the article was an adequate and effective treatment for worms in feeder cattle, and that it would benefit gaunt, undernourished off-feed cattle with irregular appetites, intermittent scouring, rough coats, watery eyes, impaired eyesight, over on the fetlocks, stiffness in gaits, swollen joints, lower extremities and briskets.

**DISPOSITION:** Vitamineral Products Co., Peoria, Ill., appeared as claimant and filed exceptions to the libel as follows: That the warrant of arrest and the return thereof was not in accordance with Admiralty Rule 10 for the United States District Court; that the venue was improper; that the place of seizure was not named; that the libel made no charges against portions of the seized article; that the libel contained a defective jurisdictional allegation; that the libel was not clearly worded; and that the grounds for forfeiture were not stated as required by Admiralty Rule 21.

On 4-6-60, the court entered an order which directed that the Government state more definitely what articles were referred to by use of the words "the aforesaid article" and "the aforesaid articles" appearing in the libel, and which overruled and denied claimant's other exceptions to the libel.

On 6-10-60, the court entered an order of default against the Vitamineral Products Co. for failure to file a claim and answer, and on 6-15-60, the court entered a default decree of condemnation and destruction.

**6200. Ancho-Dine.** (F.D.C. No. 44067. S. No. 97-795 P.)

**QUANTITY:** 63 1-lb. jars, 9 25-lb. jars, 2 100-lb. jars, at Topeka, Kans.

SHIPPED: Between 12-18-59 and 1-19-60, from St. Joseph, Mo., by the Anchor Serum Co.

LABEL IN PART: "Ancho-Dine for Veterinary Use Only \* \* \* Each Ounce Contains: Active Ingredients: Ethylenediamine Dihydroiodide 4.6% W/W \* \* \* Supplies Readily Available Iodine, Liberated Internally as Hydriodic Acid, in Therapeutic Dosage, Anchor Serum Company, Saint Joseph, Missouri."

ACCOMPANYING LABELING: Booklets entitled "Animal Health References."

LIBELED: 2-17-60, Dist. Kans.

CHARGE: 502(a)—when shipped, the labeling which accompanied the article contained false and misleading representations that the article was an adequate and effective treatment for overcoming mastitis, respiratory conditions, lumpy jaw, and other low-grade infections.

DISPOSITION: 4-7-60. Consent—claimed by Kansas Farmers Union, Topeka, Kans., and relabeled.

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<sup>1</sup> (6175) Injunction issued.

<sup>2</sup> (6199) Seizure contested.

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<sup>1</sup> (6175) Injunction issued.



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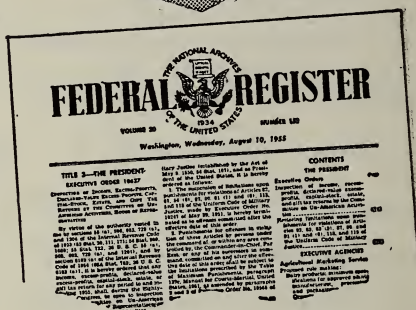
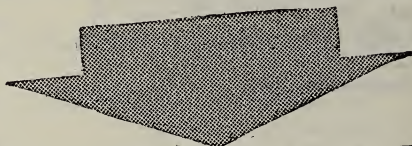
<sup>1</sup> (6175) Injunction issued.<sup>2</sup> (6199) Seizure contested.

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<sup>2</sup> (6199) Seizure contested.

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